EXHIBIT B

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY
CAMDEN VICINAGE

\- - -

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875
THIS DOCUMENT RELATES TO: Gaston Roberts et al. v. Zhejiang Huahai Pharmaceutical Co., et al.	
Case No. 1:20-cv-00946-RMB-SAK	

\- - -

May 5, 2025

\- - -

Remote videotape expert deposition of VICTORIA CHERNYAK, MD, MS, taken pursuant to notice, was conducted at the location of the witness in New York, New York, beginning at 9:02 a.m., on the above date, before Kimberly A. Cahill, a Federally Approved Registered Merit Reporter and Notary Public.

\- - -

APPEARANCES:

NIGH GOLDENBERG RASO & VAUGHN, PLLC
BY: C. BRETT VAUGHN, ESQUIRE
BY: DANIEL A. NIGH, ESQUIRE
BY: KATHRYN AVILA, ESQUIRE
14 Ridge Square NW
Third Floor
Washington, D.C. 20016
(202) 792-7927
bvaughn@nighgoldenberg.com
dnigh@nighgoldenberg.com
kavila@nighgoldenberg.com
Representing the Plaintiffs

KIRKLAND & ELLIS, LLP
BY: NINA ROSE, ESQUIRE
1301 Pennsylvania Avenue, N.W.
Washington, D.C. 20004
(202) 389-3394
nina.rose@kirkland.com
Representing the Defendant, Zhejiang Huahai Pharmaceutical Co., Ltd.

KIRKLAND & ELLIS, LLP
BY: AUDREY ASPEGREN, ESQUIRE
601 Lexington Avenue
New York, New York 10022
(212) 446-4800
audrey.aspegren@kirkland.com
Representing the Defendant, Zhejiang Huahai Pharmaceutical Co., Ltd.

VIDEOTAPE TECHNICIAN:
William Geigert

ALSO PRESENT:
Stephanie Iken
Nigh Goldenberg Raso & Vaughn, PLLC

- - -

- - -

INDEX

- - -

Testimony of: VICTORIA CHERNYAK, MD, MS

- - -

EXHIBITS

- - -

- - -

DEPOSITION SUPPORT INDEX

- - -

Direction to Witness Not to Answer
Page Line Page Line Page Line

Request for Production of Documents
Page Line Page Line Page Line

Stipulations

Page Line Page Line Page Line

Question Marked
Page Line Page Line Page Line

Page 6

- - -

THE VIDEO TECHNICIAN: Good morning. We are now on the record. My name is Bill Geigert. I'm a videographer for Golkow, a Veritext Division. Today's date is May 5th, 2025 and the time is 9:02 a.m.

This remote video deposition is being held in the matter of Valsartan, Losartan, and Irbesartan Products Liability Litigation for the United States District Court for the District of New Jersey. The deponent is Dr. Victoria Chernyak.

All parties to this deposition are appearing remotely and have agreed to the witness being sworn in remotely. Due to the nature of remote reporting, please pause briefly before speaking to ensure all parties are heard completely.

Page 7

All counsel will be noted on the stenographic record. The court reporter is Kim Cahill and she will now swear in the witness.

- - -

VICTORIA CHERNYAK, MD, MS, after having been duly sworn, was examined and testified as follows:

- - -

EXAMINATION

- - -

BY ATTORNEY VAUGHN:

Q. Dr. Chernyak, have you ever been deposed before?

A. Yes.

Q. In what matters have you been deposed before?

A. I was named in a malpractice lawsuit, so I was deposed during that.

Q. Have you ever served as an expert witness before?

A. No, sir.

Q. Just some base rules you probably know from your prior deposition.

Page 8

We'll try not to talk over each other so that the court reporter can get a clean transcript.

Does that make sense?

A. Yes, sir.

Q. I'll do my best not to interrupt you when you're answering. We are on Zoom and if, you know, there's a break in your cadence, I might accidentally interrupt you. I apologize if I do. I'll let you finish your answer.

Like you just did, you know, give yes or no answers or full answers as opposed to nodding or shaking your head so the court reporter can get a transcript.

Does that make sense?

A. Yes, sir.

Q. And then when I ask questions, like they were saying, pause for a second before you answer so that Nina has a chance to launch her objections.

Page 9

Does that make sense?

A. Yes.

Q. And then I typically take breaks every hour or so. I drink coffee. It looks like you are as well. So if you ever need a break, let me know. As long as we're not, like, in mid-question or right with a document, we'll take a break probably right then or as soon as I finish my line of questioning.

Okay?

A. Yes.

Q. Did you bring any notes with you today?

A. In electronic form.

Q. What notes did you bring with you in electronic form?

A. I brought a copy of my report and copy of my exhibits.

Q. Are there actual notes on your report or is it just a printed copy of your report and exhibits?

A. Printed a copy -- well, not printed, just --

Page 10

Q. An electronic copy.
A. Yes.
Q. I'm sorry. I didn't mean to talk over you just then.
Do you have any programs open on your computer besides the Zoom and whatever you're using to view those documents?
A. I have a browser open with a link to the remote files where the files will be dropped if we need them.
Q. Understood. You don't have any messaging programs open; correct?
A. No.
Q. Is there anyone else in the room with you?
A. No humans.
Q. Is there a cat?
A. There's a dog. I apologize if she starts snoring.
Q. I do not want to know any conversations you had with your attorneys, but did you prep with the attorneys before today?

Page 11

A. Yes.
Q. And approximately how many days did you prepare with the attorneys for this deposition?
ATTORNEY ROSE: Object to the form.
ATTORNEY VAUGHN: Let me reask -- let me reask that. I'm sorry.
BY ATTORNEY VAUGHN:
Q. Approximately how many different times did you prepare with the attorneys today for this deposition?
A. Four or five.
Q. And approximately how many hours in total did you prepare with the attorneys for this deposition?
A. I have it written down. Maybe like six or seven hours?
Q. Okay.
A. Maybe less. I have to look it up on my notes.
Q. And which attorneys were present in your preparation?

Page 12

A. Ms. Rose and one of her associates whose name I don't remember.
Q. Prior to being retained for this litigation, were you familiar with the substance N-nitrosodimethylamine, which is also abbreviated NDMA?
A. No.
Q. Have you made yourself familiar with that substance in the course of this litigation?
A. No.
ATTORNEY VAUGHN: Kathryn, can we drop the invoice in for Exhibit 1?
- - -
(Deposition Exhibit No. Chernyak-1, 4/24/25 Invoice of Victoria Chernyak, MD, MS, was marked for identification.)
- - -
THE WITNESS: Refresh now?
ATTORNEY AVILA: Yes, it should be in there now.
ATTORNEY VAUGHN: And I'm

Page 13

going to screen-share as well, but feel free at any time to pull the documents up yourself to look through them.
BY ATTORNEY VAUGHN:
Q. And is what I'm sharing, is this the invoice that you produced for your Notice of Deposition?
A. Yes, sir.
Q. And was there a reason you didn't start reviewing materials for your report until 3/27/2025?
A. Yes. I was away at a conference, so I told the counsel right had away I won't be able to do anything until the conference is done.
Q. And 4/8/25 is when you finalized your report?
A. Yes, sir.
Q. So would you say you started working on your report 3/27/25?
A. That's when I started reviewing the materials.
Q. So in total, would you say

Page 14

that you spent 9.75 hours on your actual report?
A. Whatever that number comes out to be, yes -- 1, 2, 3, 4, 5, 6, 7 -- yep.
Q. Okay.
A. 10 -- 10.25.
Q. You started with reviewing materials; correct?
A. Yes.
Q. What materials did you review?
A. I reviewed the CT and MR from 2016 and 2018, respectively. I've reviewed the Dr. Mele and Dr. Siddiqui's reports, and I've referenced any additional imaging that was relevant -- that I found relevant at the time of review.
Q. And you didn't review any of the general causation expert reports; correct?
ATTORNEY ROSE: Object to the form.

Page 15

THE WITNESS: I didn't -- I didn't review what?
ATTORNEY VAUGHN: Any general causation expert reports?
THE WITNESS: I'm not sure what that is.
BY ATTORNEY VAUGHN:
Q. The only two expert reports you reviewed were Dr. Siddiqui's and Dr. Mele's; correct?
A. Those are the two reports that I referenced in detail.
Q. Are you aware if any defense experts relied on your expert report?
A. Can you ask that -- can you say that one more time?
Q. Are you aware if any of the defense experts relied on your expert report?
A. No.
Q. Do you know who Dr. Mohmed is?
ATTORNEY ROSE: Object to the form.

Page 16

THE WITNESS: I think that's the hepatologist?
BY ATTORNEY VAUGHN:
Q. Have you ever talked to Dr. Mohmed?
A. No.
Q. Did you review any medical records specific to Mr. Roberts outside of his scans?
A. Outside of his scans, I -- I think there was a link to them, but I didn't review them.
Q. Do you know Mr. Roberts' past medical history?
A. Only as it pertains to the CT and MR that I've reviewed.
Q. And so what past medical history are you aware of based on that?
A. I believe he had fatty liver disease.
Q. And is that all you're aware of?
A. Yes.
Q. Did you do a literature

Page 17

review?
A. In my life, yes, many times.
Q. As part of this expert report, did you do a literature review?
A. I -- yes.
Q. Can you describe your literature review?
A. It's -- what specific -- like, can you just make it more -- like, what -- there's a PubMed. A lot of literature that I cited, I've read many times and have cited in many of my works, so I knew what I was looking for, so I would go into PubMed for most of the cited papers.
I knew the -- either the name of the papers, the main authors, I would go into PubMed, put that in, find the relevant article that I needed, provide -- provide a citation.
Q. Did you have to re-review what you felt like were relevant articles or were you already familiar with them?
ATTORNEY ROSE: Object to

Page 18

the form.
THE WITNESS: I was very familiar with most of them and if I needed specific numbers, precise numbers, then I reviewed them.
ATTORNEY VAUGHN: Will you drop her expert report in next, Kathryn? This will be Exhibit 2.
- - -
(Deposition Exhibit No. Chernyak-2, Expert Report of Victoria Chernyak, MD, MS, was marked for identification.)
- - -
ATTORNEY AVILA: Yes, it should be in there now.
BY ATTORNEY VAUGHN:
Q. And is this your expert report, Dr. Chernyak?
A. Yes, sir.
Q. 83 pages total counting your exhibits?
A. Yes.
ATTORNEY ROSE: Mr. Vaughn,

Page 19

I just want to confirm with the witness that she has the full exhibit in the exhibit share and not just what you're showing on your screen.
ATTORNEY VAUGHN: Not a problem. I think she has it printed, too.
THE WITNESS: I do. It's my report and -- and there is my C.V., which probably takes up most of the 83 pages, and it's my exhibit -- I'll get there -- Exhibit B are the images and Exhibit C are -- and D -- yep, I have it all.
BY ATTORNEY VAUGHN:
Q. And before we start going through all of your expert report, are there any corrections you would like to make to your expert report, any errors?
A. Yes. There was a typo with a date of CT. I said it was April 8, 2016. It's actually April 19th.

Page 20

Q. Can you point me to -- is that on page 3 we're talking about?
A. That is on page -- the pages are not numbered. Under section B, it says review of imaging examination.
Q. (Indicating.)
A. That's it, yep.
Q. Right here, so this was the first mistake?
A. Yep.
ATTORNEY ROSE: Object to the form.
BY ATTORNEY VAUGHN:
Q. And is this a mistake again where you have this date here, April 8, 2016 is the wrong date again?
A. A typographical mistake, yes.
Q. Does this mistake appear throughout your report or is it just right here twice?
A. Wherever the date was that's the date that --
Q. Okay.

Page 21

A. Wherever I mention specific date. I think in some places I just say April 2016, so that's correct, but the number 8 is incorrect. It's the 19th.
Q. And what caused you to get the date wrong?
A. I think I have dyslexia to numbers, so sometimes I mix them up.
Q. So was it supposed to be 8/4/2016?
A. It was supposed to be April 19th, 2016. So I -- I don't remember the numbers very well, so I probably looked -- glanced at a different date.
Q. Is there any other studies that were done on this date, April 8th, 2016, to your recollection?
A. The ultrasound, ultrasound.
Q. And did you review the ultrasound?
A. I did.
Q. Is there a reason you don't discuss the ultrasound anywhere in your expert report?

A. It was not contributory to my opinion.
Q. What do you mean by that?
A. It -- the opinions that I've provided are based on CT and ultrasound didn't add or added those opinions or -- it was not relevant to my opinion.
Q. Did the ultrasound go against your opinion?
A. No.
Q. Is there any other errors that you notice in your expert report?
A. No, sir.
Q. When did you last review your expert report?
A. This morning.
Q. Did Mr. Roberts undergo an MRI in April of 2016?
A. Yes, he did undergo MRI in April 2016.
Q. He did?
A. I'm sorry. August '16.
Q. Can you tell me about that MRI he underwent in 2016?

A. It was a standard multiphase MRI with a standard protocol which is utilized for assessment of multiple abdominal pathologies, but in this case specifically was done to evaluate liver lesions which were noted on the CT that was done a few days -- within the week of that MRI.
What -- how much more details do you want me to go into?
Q. An MRI gives better imaging than a CT; correct?
A. No. It's -- well, it's not a yes or no question. It depends on which -- it depends on really multiple factors, including what pathology we're looking at, patient factors, lesion location.
So it's -- for some situation, the answer is yes. For some situation, the answer is no.
Q. Does an MRI have a higher specificity of diagnosing cancer than a CT?

A. That is not a categorical correct statement. So, again, as I mentioned, it depends on the type of cancer. It depends on the type of patient. For some cancers, generally, the statement is yes. For some cancers, generally, the statement is no.
Also, a lot of patient factors, right, if the patient -- if the patient cannot hold still and cannot comply with a quiet breath holding, then generally MRI will be far less diagnostic than a well-conformed CT.
Q. Would you agree that this 2016 MRI was important to your expert opinion?
A. 2000 --
ATTORNEY ROSE: Object to the form. Mr. Vaughn, clearly that there is a typographical error here that I think --
ATTORNEY VAUGHN: Excuse me.
ATTORNEY ROSE: Okay.
THE WITNESS: Okay.

ATTORNEY VAUGHN: No more speaking objections in this. I've made it very clear on my questions. Do not coach your witness.
THE WITNESS: It was an -- okay -- typographical error --
ATTORNEY VAUGHN: Now you're saying typographical error after your attorney said it's a typographical error.
THE WITNESS: However the lesion's -- however's the lesion's present on April -- okay. It was supposed to be CT --
BY ATTORNEY VAUGHN:
Q. What's supposed to be CT?
A. Instead of MRI, it's supposed to be CT.
Q. So this is another error in your expert report?
A. Another error -- typographical error, yes.
Q. Were you in a rush when you

Page 26

were doing your expert report?
A. No.
Q. And so you haven't talked to Dr. Mohmed. Right?
A. No.
Q. Did you let Dr. Mohmed know there wasn't actually a CT in 2016, like you say in your expert report?
ATTORNEY ROSE: Object to the form and this is becoming harassing.
THE WITNESS: I mean, I -- there is an entire -- part of my report talks about 2016 CT. Part of my report talks about MRI. So --
BY ATTORNEY VAUGHN:
Q. Part of your report says the CT was on the wrong date and part of your report calls the CT an MRI; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: We already discussed this. I made a mistake

Page 27

in the date.
BY ATTORNEY VAUGHN:
Q. And on the type of imaging that was done. Right?
ATTORNEY ROSE: Object to the form.
THE WITNESS: In one sentence.
BY ATTORNEY VAUGHN:
Q. And these are the materials that you considered for your expert report?
A. Yes.
Q. And you're the author of one of these articles. Right?
A. Yes.
Q. And you author a lot of articles on LI-RADS?
A. LI-RADS, yes.
Q. LI-RADS. Thank you.
That's the only study of yours or literature on LI-RADS that you considered?
A. The paper that says Lee,

Page 28

Sunyoung, percentages, I am one of the authors on that paper.
Q. Where's that at -- right down here?
A. Yep.
Q. Okay. And have you published other literature on LI-RADS?
A. Yes.
Q. And is that literature consistent with your opinions in this report?
A. Yes.
Q. And you reviewed these deposition transcripts, Dr. Hooks and Dr. Lockhart?
A. Briefly, yes.
Q. And you didn't review any pharmacy records for Mr. Roberts, did you?
A. No.
Q. Do you have any idea of the total amount of NDMA he was exposed to?
A. No.
ATTORNEY ROSE: Object to

Page 29

the form.
THE WITNESS: No.
BY ATTORNEY VAUGHN:
Q. Is the earliest imaging you reviewed 2016?
A. Yes.
Q. Do you know if Mr. Roberts had HIV?
A. No.
Q. Do you know if Mr. Roberts had hep B?
A. My understanding is, no, that was not mentioned.
Q. In your opinion, did Mr. Roberts have cirrhosis?
A. On which date?
Q. 2016.
A. Yes.
Q. Do you believe that Mr. Roberts had significant cirrhosis as of 2016?
A. Significant cirrhosis is not a medical term, so I'm not sure how to answer that question.

Page 30

Q. Do you believe that Mr. Roberts had advanced cirrhosis in 2016?
A. Mr. Roberts had imaging features of cirrhosis which were detectable by CT. He also had evidence of portal hypertension, so he -- his cirrhosis was enough to cause portal hypertension.
Q. And you say he has features of cirrhosis. As a radiologist, do you make the actual diagnosis of cirrhosis?
A. I -- as a radiologist, we provide things like -- statements like morphologic features consistent with cirrhosis.
Q. And then who makes the actual diagnosis of cirrhosis?
A. It -- you know, clinical picture. Sometimes patients get biopsies. Sometimes this is enough to make the diagnosis.
Q. Did any of Mr. Roberts' treaters diagnose him with cirrhosis, if you know?

Page 31

A. I'm not sure.
Q. So you didn't look through the medical records to see if his actual treating physicians didn't or did diagnose him with cirrhosis?
ATTORNEY ROSE: Object to the form.
THE WITNESS: That was not relevant to what I was asked to do, so I focused on things that were relevant to what I was -- the opinion that I was provide -- was asked to provide.
BY ATTORNEY VAUGHN:
Q. And so it wouldn't change your opinion in any way if his treating physicians did not think he had cirrhosis in 2016?
ATTORNEY ROSE: Object to the form.
THE WITNESS: No.
BY ATTORNEY VAUGHN:
Q. In your opinion, did Mr. Roberts have liver damage as of 2016?

Page 32

A. Yes. Liver cirrhosis is a advanced form of liver damage.
Q. In your opinion, did Mr. Roberts have significant liver disease as of 2016?
A. Again, significant liver disease is not a medically defined term, so I'm not sure how to answer that.
He had a cirrhosis in 2016 which was a -- was advanced enough to cause portal hypertension.
Q. Is there only one potential cause of portal hypertension?
A. No.
Q. And you didn't review all of Mr. Roberts' medical records, did you?
A. No.
Q. Did Mr. Roberts have liver disease in your opinion in 2016?
A. Yes.
Q. As of 2016, did Mr. Roberts have a weakened liver?
A. I'm not -- again, this is not a medically defined term, so I don't

Page 33

know how to answer that question.
Q. Does a liver disease weaken one's liver?
A. I -- you have to define what you mean by weaken liver.
Q. Make one's liver more susceptible?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Susceptible to what?
ATTORNEY VAUGHN: Make one's liver more susceptible to a carcinogenic exposure.
ATTORNEY ROSE: Object to the form.
THE WITNESS: Not -- not to my knowledge. I -- I have no knowledge to answer this question, I have no knowledge.
ATTORNEY VAUGHN: Kathryn, let's drop in that 4/8/2016 ultrasound.
ATTORNEY AVILA: Okay. This

Page 34

is Exhibit 3.

- - -

(Deposition Exhibit No. Chernyak-3, 4/8/16 Report of Ultrasound for Gaston J. Roberts, was marked for identification.)

- - -

ATTORNEY ROSE: Doctor, can you see the whole document on your exhibit viewer?

THE WITNESS: Yes.

BY ATTORNEY VAUGHN:

Q. And this ultrasound was taken 4/8/2016; correct?

A. Yes.

Q. This is the date that you said a CT was done?

A. Yes.

Q. And you have reviewed this ultrasound report; correct?

A. Yes.

Q. Did you review the native ultrasound files yourself or just this report?

Page 35

A. I looked at the images, yes.

Q. And you see that there was a comparison to a 2009 ultrasound?

A. Uh-hum.

Q. Did you review that ultrasound?

A. I did not have images of that ultrasound provided for me.

Q. But the radiologist that was treating Mr. Roberts as of 2016 would have had access to that; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: I presume that the report said comparison, that means that that report was available.

BY ATTORNEY VAUGHN:

Q. And so they were comparing it to a prior one, but you were unable to do that; correct?

A. Correct.

Q. And two solid densities are noted on this ultrasound; correct?

Page 36

A. Yes.

Q. Measuring 2 centimeters and 1.8 centimeters?

A. Yes.

Q. In your opinion, were these cancerous?

A. This is not something that can be answered based on ultrasound.

Q. Based on the subsequent imaging, did you see these densities?

ATTORNEY ROSE: Object to the form.

THE WITNESS: Can I proceed?

ATTORNEY ROSE: Yes.

THE WITNESS: There were no -- no corresponding lesions on the subsequent CT that I could correlate to these lesions.

BY ATTORNEY VAUGHN:

Q. Would this therefore be considered a negative ultrasound?

A. No.

Q. And can you explain that?

A. The ultrasound demonstrating

Page 37

-- demonstrated findings. These findings were visible, so you can't say it's negative.

Subsequent CT did not demonstrate a corollary to these findings, but that doesn't make the ultrasound negative.

Q. So in your opinion, are these two densities cancerous?

ATTORNEY ROSE: Object to the form.

THE WITNESS: This is not -- these are indeterminate, as stated in the -- I completely report it -- if we see something on ultrasound that is indeterminate, we have to follow up with CT, they follow up with CT.

BY ATTORNEY VAUGHN:

Q. And the follow-up on CT determined that these were not cancerous; correct?

A. The follow-up CT did not find a lesion that corresponded to these

2 centimeter lesions.
Q. And so you wouldn't be able to say to a reasonable degree of medical certainty that these two lesions were cancerous; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Can you repeat the question?
BY ATTORNEY VAUGHN:
Q. You can't say to a reasonable degree of medical certainty that these two lesions were cancerous; correct?
A. Correct.
ATTORNEY VAUGHN: Kathryn, can we go to the 4/19/2016 CT next?
ATTORNEY AVILA: Yes, and this is Exhibit 4.
- - -
(Deposition Exhibit No. Chernyak-4, 4/19/16 Report of CT Abdomen WO/W Contrast for Gaston

J. Roberts, was marked for identification.)
- - -
BY ATTORNEY VAUGHN:
Q. And so this is the CT you were referring to that was actually done on 4/19/2016; correct?
A. Correct.
Q. And when they did it, they compared it to the ultrasound on that 4/8/2016. Did you also compare it to that ultrasound when you were reviewing this?
A. Yes.
Q. And is this 8 millimeter lesion the only one that is detected in this CT?
ATTORNEY ROSE: Object to the form.
ATTORNEY VAUGHN: I'll reask it.
BY ATTORNEY VAUGHN:
Q. Is this 8 millimeter lesion the only lesion that is detected in this

C.V.?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Can you actually zoom in? This is a little too small --
ATTORNEY VAUGHN: I can. And if you need to download it and review it in more detail, please, take your time.
THE WITNESS: That's fine, no, no. This is the only lesion that is described on the report.
BY ATTORNEY VAUGHN:
Q. And in your opinion, does this 8 millimeter lesion go on to become cancer?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I have formed my opinion based on reviewing the images, not this report, so actually the report is -- does not specify which of the -- I actually

see three lesions on the CT, so I'm not sure which one of these they are specifically referencing.
BY ATTORNEY VAUGHN:
Q. Did you see any lesion that was 8 millimeters in size?
ATTORNEY ROSE: Object to the form.
THE WITNESS: The largest lesion that I've measured was 6 millimeters.
BY ATTORNEY VAUGHN:
Q. So is the answer to my question, no, you did not see this 8 millimeter lesion that is described?
A. It's a 2 millimeter measuring difference, so it's quite possible that what I measured as 6 millimeters, they measured at 8 millimeters.
Q. Does that also mean that what you measured at 6 millimeters could be measured at 4 millimeters?
A. Unlikely.

Page 42

Q. Why is that?
A. The 4 millimeter difference is -- is more than 2 millimeters.
Q. But you measured it at 6 millimeters; correct?
A. Yes.
Q. And isn't 4 two less than six?
A. Is 4 two less than six?
Q. It's 6 minus 2.
A. Yes.
Q. So why can't it -- why can't your measurement be off 2 to the bottom as opposed to -- as opposed to 2 to the top?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I provided the images with my measurements and calipers on. You can judge for yourself if my measurements is off.
BY ATTORNEY VAUGHN:
Q. Is 2 plus or minus a normal

Page 43

range?
A. Millimeters?
Q. Yeah.
A. There's -- there's always a measurement error that we reference in radiology report that sometimes, you know, we have to say that -- like, if you're looking at the follow-up and you're making a determination if something grew or not, sometimes you can say that the differences is measurement or differences in reports is maybe due to measurement error. That's...
Q. Is there some subjectivity in measurement?
A. Minimal, but some, especially when we're talking about such lesions, such tiny lesions.
Q. And you see here where the radiologist finding was, nonspecific findings may be evidence of liver cirrhosis? Is that consistent with your opinion?
A. My opinion is that he had

Page 44

cirrhosis at this time in the scan.
Q. And is that how you would normally say it as a radiologist when you're reading a report? You would actually diagnose him with cirrhosis as opposed to saying that it is consistent with cirrhosis?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Consistent with represent 90 percent probability that -- not the probability -- 90 percent confidence in my subjective scale. So when I say consistent with, I'm about 90 percent confident in the diagnosis.
BY ATTORNEY VAUGHN:
Q. And that's a suggestive scale?
A. Well, interesting you should ask. It -- yes and no. I use the objective scale that was set upon forth by Memorial Sloan Kettering Cancer

Page 45

Center, so I use very defined certainty scale.
It's not adopted by every radiologist everywhere, but that is the scale that I use.
Q. And is that scale considered diagnostic?
A. That scale provides interpretation of certainty lexicon, so there are only specific words that are used to provide certainty in diagnosis. And based on that scale, consistent with means that radiologist is about 90 percent -- 70 to 90 percent confident in diagnosis.
Q. Do you see where he says no other focal liver -- scratch that.
Do you see where it says: No other focal liver lesions are seen?
A. Yes.
Q. You disagree with that; correct?
A. Yes.
Q. You saw liver lesions that

the radiologist treating Mr. Roberts did not see; correct?
A. Correct.
Q. How many additional liver lesions did you find?
A. Two more, so I saw three in total.
Q. Did you look for any other liver lesions throughout his liver?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I mean, I looked through the liver, the entire liver.
BY ATTORNEY VAUGHN:
Q. And you didn't find any other lesions besides those three?
A. Those are three that I found.
Q. If you found other ones that were similar, would you have noted those as well?
A. I hope so.
Q. Would it make a difference

if he had more liver lesions than the three that you saw?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Make a difference to what?
ATTORNEY VAUGHN: Your opinion.
THE WITNESS: No.
BY ATTORNEY VAUGHN:
Q. If he had a lot of the same liver lesions, would that decrease the chance or increase the chance that they were carcinogenic?
ATTORNEY ROSE: Object to the form.
THE WITNESS: No.
BY ATTORNEY VAUGHN:
Q. So the number of lesions present is irrelevant to the risk of it being HCC; correct?
(Pause.)
THE WITNESS: It depends.
BY ATTORNEY VAUGHN:

Q. What does it depend on?
A. It depends on appearance of the lesions and...
Q. If he had a lot more lesions that looked the exact same, would it be more or less likely that he had cancer?
ATTORNEY ROSE: Object to the form.
THE WITNESS: It depends how many. If his entire liver was replaced by nodules and they all look identical -- and I'm talking about entire liver -- then we would probably just say these are cirrhotic nodules.
BY ATTORNEY VAUGHN:
Q. And you didn't see additional nodules?
A. No.
Q. Not even in that frame 24?
ATTORNEY ROSE: Object to the form.
THE WITNESS: In what?
ATTORNEY VAUGHN: I'll go

back to it later.
BY ATTORNEY VAUGHN:
Q. Do you have any critiques of this CT?
A. What do you mean?
Q. Was this an ideally done CT in your opinion?
A. It was done with appropriate required protocol with and without contrast with arterial phase, portal venous phase, and delayed.
THE COURT REPORTER: I'm sorry. Can you repeat that?
THE WITNESS: It was done in compliance with what LI-RADS recommends to have a multiphase CT.
BY ATTORNEY VAUGHN:
Q. Can you tell the jury what LI-RADS recommends on a CT?
A. LI-RADS recommends at least arterial phase, which was obtained in this case, portal venous phase, and the precontrast images in this context are

Page 50

optional. In this case, they were obtained.
Q. You're a professor; correct?
A. Yes.
Q. Were you previously a radiology professor at Harvard?
A. At Harvard, I was associate professor.
Q. Associate? And where are you a professor of radiology now?
A. Columbia.
Q. And would you tell your students that this was an appropriate CT to apply LI-RADS to?
A. Yes.
Q. Would you tell them this is an ideal CT to apply LI-RADS to?
A. Define "ideal."
Q. Are there better CTs that would be more appropriate to apply LI-RADS to?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I'm really not

Page 51

sure what you mean by more appropriate. It was done with correct protocol.
BY ATTORNEY VAUGHN:
Q. And can you please explain that protocol to me again? I was trying to -- the realtime was a little jumbled. You said there's a portal venous phase and a what phase?
A. Arterial phase.
Q. So there's two phases that LI-RADS needs in a CT?
A. At least two phases: Arterial phase, portal venous phase, delayed phase. And then precontrast is required if patient had prior treatment. In cases like this, the precontrast is optional. In this case, it was obtained.
Q. So is there three phases to this CT?
A. I don't remember if -- I believe there -- there was definitely arterial and portal venous phase and pre. I'm blanking if there was delayed. I

Page 52

believe so.
Q. Out of those three phases, which three would be the -- which one would be the most important phase?
A. Well, arterial phase is crucial, but --
Q. Why is arterial phase crucial?
A. Because presence of arterial phase hyperintense enhancement is a required feature to diagnose HCC noninvasively.
Q. You said hyperenhancement is a required feature to diagnose HCC noninvasively; correct?
A. Yes, sir.
Q. And then what was the second phase?
A. Portal venous phase.
Q. And is that an important phase?
A. Yes.
Q. Why is that phase important?
A. Because -- because you need

Page 53

multiphase -- I mean -- because in order to diagnose HCC, we need to assess for at least five features.
Do you want me to go through them?
Q. Please.
A. Size, arterial phase hyperenhancement, washout which is assessed either in portal venous phase or in delayed phase, enhancing capsule, and threshold growth.
Threshold growth has a very specific definition and it has to be prepared to an appropriately performed study bound within six months of original study, so if no ascites present, we consider threshold growth as absent, as in this case.
Arterial phase hyperenhancement is only assessable on arterial phase. It is a required feature to diagnose a lesion as a HCC noninvasively. Size of 10 millimeter is required to diagnose something as HCC

Page 54

noninvasively.
Portal venous phase and/or delayed phase is necessary to assess something as having washout and enhancing capsule.
Q. I'm sorry. What's the third phase?
A. Delayed phase.
Q. And why is that phase necessary?
A. It may be necessary because sometimes small HCCs don't wash out until delayed phase. But if you see washout in portal venous phase, that's enough.
Q. If you have no wash-in, can you have washout?
A. Yes.
Q. Explain that.
A. According to LI-RADS definition, the arterial -- if the lesion is iso-enhancing in the arterial phase and then hypoenhancing on subsequent phase, that is sufficient to call washout.

Page 55

Q. What is --
THE COURT REPORTER: I'm sorry. Can you just -- can you just go a little bit slower? Thank you.
THE WITNESS: I'm sorry. LI-RADS provides very specific definition of washout. For washouts to be present, the lesion has to be either iso or hyperenhancing on earlier phase and then become hypoenhancing on subsequent phase.
So one of the ways that lesion can have washout is iso-enhancing on arterial phase and hypoenhancing on portal venous phase.
BY ATTORNEY VAUGHN:
Q. What is iso-enhancing?
A. Enhances identical similar to the background parenchyma.
Q. So it's enhancing the same as the liver?

Page 56

A. Yes.
Q. And that's enough for you then to later say there's washout?
A. No. As I said, you need two components. You need either iso or hyperenhancing early on and then hypoenhancing later on.
Q. What's a stronger indication of washout, if you have iso-enhancing or hyperenhancing initially?
A. It doesn't matter. Both are acceptable definitions of washout.
Q. Can you have hypoenhancement and washout in the same lesion in the same image at the same time?
A. Can you say that again?
Q. Can you have hypoenhancement and washout of the same lesion in the same image at the same time?
ATTORNEY ROSE: Object to the form.
THE WITNESS: The definition of washout is -- requires two phases. So, technically, if you

Page 57

have only one phase, technically, if you want to be a stickler, which I am, washout is not diagnosable. So you need at least two phases to diagnose washout, to characterize something as having washout.
BY ATTORNEY VAUGHN:
Q. And so you cannot have hypoenhancement and washout in the same phase; correct?
A. I'm not sure that -- what you're asking me. If I see a portal venous phase and the lesion is hypoenhancing, that's part of washout definition.
So you have to have hypoenhancement to say something has washout.
Q. But they would have to be in two different phases; correct?
A. You need to have an earlier phase showing something is iso or hyperenhancing to precisely say

Page 58

something's washout.
Q. Was his lesion visible in phase one to you?
ATTORNEY ROSE: Object to the form.
THE WITNESS: It was iso-enhancing to me.
BY ATTORNEY VAUGHN:
Q. To you.
A. To me.
Q. Is that a subjective determination?
A. It is -- it is a qualitative assessment and therefore by definition has some subjectivity.
Q. And what's the subjectivity in that?
A. That I with my eyes look at the lesion and compare it to background and determine if it's iso/hypo. According to the -- according to the literature, the -- you know, there's moderate interreader agreement for qualitative imaging features and that is

Page 59

true for pretty much any qualitative imaging features. That's probably as best as humans can agree on qualitative imaging features.
CAPAs are around high .6, low .7. I'm happy to provide you with references for that statement.
ATTORNEY VAUGHN: We can be done with this for a second. Go back to your expert report, which was Exhibit 2.
BY ATTORNEY VAUGHN:
Q. I'm looking at the second paragraph, it's the first full paragraph on the third page. You say: Diagnostic LI-RADS includes seven diagnostic criteria -- categories --
A. Yes.
Q. -- each representing a diagnostic certainty of HCC verse -- benignity?
A. Benignity, yep.
Q. So what does this mean?
A. That each category provides

Page 60

a probability that the lesion is HCC. The probabilities are defined by multiple meta-analysis.
So if I say, you know, LR-1 definitely benign, that means that lesion has zero probability of being malignant and 100 percent probability of being benign.
If I say that LR-5, right, LI-RADS 5, definite HCC based on the literature, the probability that this lesion is HCC is 95 percent. Probability that this lesion is malignant is about 99 percent.
Q. The only diagnostic parts of LI-RADS are LI-RADS 1 and 5; correct?
A. No. That's incorrect. LI-RADS -- each category provides a defined probability. Right? So LR-M probably or definitely malignant non-HCC specific, 99 percent malignancy -- probability of malignancy. Of them, about 67 percent are HCC. The rest are mostly non-HCC malignancy.

Page 61

LI-RADS tumor vein -- definite tumor vein -- 100 percent malignancy rate, 70 to 85 percent HCC.
Q. You didn't put a citation for this sentence, did you?
A. I did.
Q. What citation goes with this sentence?
A. I believe number 6 -- no, wait. Not number 6. Number 7.
Q. Number 7.
A. Both 6 and 7 -- you can use both 6 and 7 for that. But 7 provides -- is a meta-analysis which looks at all the different probabilities and provides all these numbers.
Q. So this 2018 article is what you're citing for there being seven different diagnostic categories?
A. Yes.
ATTORNEY ROSE: Object to the form.
BY ATTORNEY VAUGHN:
Q. And you agree with that that

Page 62

this supports that there's seven different diagnostic categories?
A. For diagnostic LI-RADS, yes.
Q. Can we go to page 5 of your expert report?
A. Which one is that? Because my number -- they're not numbered.
Q. PDF page 5. It's the one where you have -- you identify different segments that you see lesions.
A. Okay.
Q. And, again, you noted it was an April 8th, 2006 CT. This was supposed to be that later date of --
A. 18 -- 18? 19? 19.
Q. 19th? Okay.
This first lesion, this .6 centimeter --
A. Uh-hum.
Q. -- you're not saying that this turned into cancer; correct?
ATTORNEY ROSE: Object to the form.
ATTORNEY VAUGHN: You can

Page 63

still answer.
THE WITNESS: I -- can you rephrase your question, please?
BY ATTORNEY VAUGHN:
Q. Yeah, this .6 centimeter lesion that you detected, you then looked in the 2018 CT; correct?
A. Yes.
Q. In your opinion, did this 6 centimeter lesion in image 17 turn into cancer?
A. 0.6 centimeter lesion.
Q. Thank you.
A. Without interim imaging between 2016 and 2018, I don't -- I cannot say definitively, but I cannot rule it out.
Q. Was there any cancer in the spot of where this .6 centimeter lesion was in image 17?
ATTORNEY ROSE: Object to the form.
THE WITNESS: That lesion met criteria for LI-RADS 3, which

Page 64

has intermediate probability of being malignancy. About 33 percent of LI-RADS 3 lesions are HCCs, so there's a possibility that it was small HCC at the time.
BY ATTORNEY VAUGHN:
Q. And by 2018, when you looked at the same spot, was there any HCC in that spot?
A. That spot correspond -- in that spot, there was a LI-RADS 5 lesion.
Q. You're saying the spot -- segment 7, the 0.6 centimeter in image 17, you're telling me in 2018, there was an HCC there?
ATTORNEY ROSE: Object to the form.
THE WITNESS: May I please reference my --
ATTORNEY VAUGHN: You may.
THE WITNESS: -- exhibit? Thank you.
(Pause.)
THE WITNESS: Segment 5/8

Page 65

lesion -- so segment 5/8 lesion --
ATTORNEY VAUGHN: I didn't realize I wasn't sharing.
THE WITNESS: So segment 5/8 lesion, so the next one, .5 centimeter.
BY ATTORNEY VAUGHN:
Q. Sorry. I didn't realize I wasn't scree-sharing. So I'm talking about the one in segment 6, this 0.6 centimeter on image 17, in your opinion, in 2018, was there HCC at this site?
A. Okay. So in segment 7 -- so all these three lesions, they look very similar to each other in terms of their imaging features, each and every one of them meets criteria for LI-RADS 3.
So each and every one of them has a about a third of a chance of being HCC at that time.
Q. And you are not answering my question. My question is simply, when you looked at the 2018 CT, was there HC -- excuse me?

Page 66

A. 2016 CT?
Q. No. I'm talking about the 2018. You were talking about the '16 here. You looked at the '16 and the '18; correct?
A. You said 2016 C -- okay.
Q. Okay.
ATTORNEY ROSE: I think the confusion -- Brett, the confusion is that in your question you referenced a 2018 CT.
ATTORNEY VAUGHN: Well, because that's what I'm asking her to compare.
You looked at the 2018 CT and on image 17 -- in 2016, you see this .6 centimeter and you say it's a LI-RADS 3. And then you go and you look at the 2018 and you look at where image 17 would be.
Did it correspond to where any HCC was?
THE WITNESS: So 2018 MRI.
ATTORNEY VAUGHN: MRI. Was

Page 67

there a CT in 2018?
THE WITNESS: There was, but it was not done with multiphase protocol, so it's not -- you can't apply LI-RADS to that, so --
BY ATTORNEY VAUGHN:
Q. And what's a multiphase protocol?
A. The one that has arterial phase and portal venous phase --
Q. And so if you don't -- if you don't do all the phases, you can't apply LI-RADS; correct?
A. Correct.
Q. Okay.
A. So in the lesion in segment 7, on series 401, image 17, had no corollary on MRI done in August of 2018.
Q. So this first one that you listed definitely did not turn into HCC; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: There was no

Page 68

-- it -- in 2018, there was no correlation to this lesion.
BY ATTORNEY VAUGHN:
Q. And then let's look at the bottom one, the segment 6, half centimeter, image 35, did you look to correspond that one in the MRI in 2018?
A. Yes.
ATTORNEY ROSE: Object to the form.
BY ATTORNEY VAUGHN:
Q. And in your opinion, did this one overlay with where HCC developed?
A. No.
Q. And so the one that we're left with is here in the middle, in section 5 and section 8, where there's the half centimeter on image 24. In your opinion, when you looked at the 2018 MRI, did this one overlay with where HCC developed?
A. Yes.
Q. And so it's only the middle

Page 69

one, the one in section 5 and section 8, that ended up overlaying with where HCC was; correct?
A. Yes.
Q. And that specific one, the one in segment 5 and 8 on image 24, in your opinion, had a 33 percent chance of become being HCC; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: No. It was -- it had 33 percent chance of being HCC at that particular moment.
BY ATTORNEY VAUGHN:
Q. So I want to be very clear then. This one in segment 5 and segment 8 that was a half centimeter in image 24, in your opinion, there was a 33 percent chance that that was cancerous as of 2016; correct?
A. Correct.
ATTORNEY VAUGHN: Now is a good time for a break.
THE VIDEO TECHNICIAN: Off

Page 70

the record at 9:56 a.m.

- - -

(A discussion off the record occurred.)

- - -

(A recess was taken from 9:59 a.m. to 10:12 a.m.)

THE VIDEO TECHNICIAN: We are back on the record at 10:12 a.m.

BY ATTORNEY VAUGHN:

Q. Doctor, LI-RADS is a diagnostic tool; correct?

A. Yes.

Q. I'm going back to your expert report, I'm on PDF page 5. I'm looking at that paragraph below the different lesions that you identified that we were talking about earlier.

A. Okay.

Q. And you note that these lesions do not demonstrate arterial phase hyperenhancement. And you're talking about all three of those do not exhibit

Page 71

that; correct?

A. Yes.

Q. So in all series, do these appear less dense?

ATTORNEY ROSE: Object to the form.

ATTORNEY VAUGHN: Let me rephrase.

BY ATTORNEY VAUGHN:

Q. In all the series, do these lesions appear less dense than the liver?

A. They are less dense than liver on the delayed phase, like series 401, which is labeled delayed. They are hyperenhancing, hypodense, less dense.

Q. You note that hyperenhancement is the hallmark of progressed HCC; correct?

A. Yes. Yes.

Q. Is hyperenhancement also just the hallmark of HCC?

ATTORNEY ROSE: Object to the form.

THE WITNESS: No. It's

Page 72

progressed HCC.

BY ATTORNEY VAUGHN:

Q. Can you explain why that is?

A. Early HCC does not yet -- typically, generally, most early HCCs do not yet develop enough angiogenesis -- Kim, are you okay with that word -- angiogenesis to manifest as arterial phase hyperenhancement.

So usually early HCCs are either iso or hypoenhancing on arterial phase, and generally most early HCCs fall into either LI-RADS 3 or LI-RADS 4 categories.

Q. And then you go on to say: and appeared as hypoenhancing foci on the portal venous phase, i.e., they had washout.

Can you explain that to me?

A. Yes. So by LI-RADS definition, washout is defined as a lesion which is iso or hyperenhancing on earlier phase and then becomes hypoenhancing, meaning hypodense or

Page 73

hypointense, to liver on subsequent phase.

In this case, the lesions did not have arterial hyperenhancement, but appeared hypoenhancing, hypodense, and therefore they had washout.

Q. So are you saying that in the portal venous phase, there is both hypoenhancing and washout?

A. Hypoenhancement is part of definition of washout.

Q. And so you're using hypoenhancement and washout synonymously?

ATTORNEY ROSE: Object to the form.

THE WITNESS: No. When -- when I wrote the report, I said they had washout and I was asked to spell it out and I spell it out -- spelled it out.

The fact that the lesions were hypoenhancing on portal venous and delayed phase and/or iso-enhancing in arterial phase

Page 74

allowed me to say that they had washout.
BY ATTORNEY VAUGHN:
Q. Did you say portal venous and delayed phase?
A. Yes. In this case, they're interchangeable.
Q. Why?
A. Because in this case, they're hypoenhancing on both phases. You need --
Q. Sorry.
A. You need to have hypoenhancement in only one of them, so --
Q. Which two phases are you saying are hypoenhancing?
A. Portal venous and delayed.
Q. What do you base that on?
A. Looking at the images.
Q. What part of the image do you look at to see that there was a delayed phase?
A. It's usually labeled.

Page 75

Q. And was it labeled in this case?
A. It was, yep, delayed, comma, 5 millimeter, that's what the name of series 401.
Q. And how long was the delayed phase?
A. I'm not privy to their exact protocols. Generally, delayed phase should be obtained somewhere between two to five -- two to five minutes after contrast injection.
Q. And then this 4/8/2016 was a typo again. Right? This one again should be 4/19/2016 CT?
A. Yes.
Q. But you note LI-RADS 3s are 33 percent malignant. You were discussing that earlier. Right?
A. Uh-hum.
Yes. Sorry. Yes. Apologize.
Q. Are there certain types of LI-RADS 3s that are more likely to be malignant than others?
A. That is a million-dollar question that we do not yet have an answer for, but certainly want to have an answer for, but not yet.
Q. In your opinion, are there certain types of LI-RADS 3s that are more likely to be malignant than others?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Again, we don't have data to state that -- accurately state that this type of LI-RADS 3, with these imaging features, is more likely to be malignant than -- we just dont' have -- we don't have data. There are actually NIH grant proposals that are being performed because it is an important question to ask scientifically.
As of 2025, we do not have objective criteria to say that these LI-RADS 3 lesions are going

Page 76

Page 77

to progress versus these LI-RADS 3 lesions which are going to behave more benignly.
So unfortunately I don't have scientific data to say these are okay and these are not going to be okay.
BY ATTORNEY VAUGHN:
Q. And has the National Institutes of Health told you that -- sorry. Scratch that.
Has the National Institute of Health opined that LI-RADS 3s are lacking data to determine if they are going to be malignant or not?
ATTORNEY ROSE: Object to the form.
THE WITNESS: There is -- okay. So LI-RADS 3 lesions have intermediate probability of malignancy, meaning that it's not high enough to treat and it's not low enough to dismiss.
Therefore, all LI-RADS 3

Page 78

lesions have to be followed up according to AASLD -- that's American Association for Study of Liver Diseases -- and LI-RADS have -- the management recommendation is that lesions which meet criteria for LI-RADS 3 have to be monitored every three to six months with an imaging modality, because we don't know which one of these will turn and progress and which will not.

It is, as you can imagine, a very large healthcare burden recognized by scientists, clinicians, and NIH.

Unfortunately, as of right now, we have no accurate way to predict which of the LI-RADS 3 lesions can be monitored less aggressively and which of the LI-RADS 3 lesions need to be monitored more aggressively.

As a result, all LI-RADS 3

Page 79

lesions have to be monitored every three to six months.

BY ATTORNEY VAUGHN:

Q. And that monitoring schedule is left to the treating physician to determine; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: Recommendation is every three to six months.

BY ATTORNEY VAUGHN:

Q. And is the treating physician supposed to take patient specifics into consideration?

A. I mean, if we're looking at a patient whose survival -- expected projected survival is six months, I would hope that the treating clinician won't subject the patient to unnecessary monitoring.

But in general, in a patient with, you know, sufficient life expectancy, recommendation for follow-up is every three to six months.

Page 80

Q. But it's the physician, the treating physician, that makes that determination; correct?

A. Makes a determination of?

Q. If follow-up is necessary based on that patient's clinical history.

A. The recommendations are every three to six months.

Q. Do the recommendations say to take patient specifics into consideration?

A. No.

Q. Is that a plan for future LI-RADS, to take patient specifics into consideration?

ATTORNEY ROSE: Object to the form.

THE WITNESS: No. Right now, no. We have no -- right now, we only take into consideration imaging appearance -- again, if the patient is bedbound and, you know, life expectancy is very limited, then obviously you would

Page 81

not necessarily subject this patient.

But in, again, healthy patient who's expected to survive for a substantial amount of patient, these lesions need to be followed.

BY ATTORNEY VAUGHN:

Q. Based on this 2016 imaging, would you expect that Mr. Roberts to survive for a long amount of time?

ATTORNEY ROSE: Object to the form.

THE WITNESS: I can't use imaging to determine how long he's going to be surviving.

BY ATTORNEY VAUGHN:

Q. LI-RADS does not look at patient-specific histories; correct?

A. LI-RADS looks at imaging features of a particular lesion in LI-RADS population and provides a risk stratification, which that risk stratification is used to manage the

Page 82

patient.
According to LI-RADS and AASLD, patients who have LI-RADS 3 observation need to be followed up every three to six months. THE decision if it's three months or six months is left to the physician, conversation with patient, but they have to be followed up.
Q. You can't diagnose a patient with HCC based on a LI-RADS 3; correct?
A. LI-RADS 3 provides an intermediate probability of being malignant, so LI-RADS 3 is about 33 percent of being malignant.
Q. And so you can't say to a reasonable degree of medical certainty that the lesion in segment 5 and segment 8 on image 24 was HCC at the time in 2016; correct?
A. It had a probability -- it had a 33 probability of being malignant.
Q. Can you say to a reasonable degree of medical certainty that it was malignant in 2016?

Page 83

ATTORNEY ROSE: Object to the form.
THE WITNESS: What's a reasonable degree? Is 33 percent reasonable degree? I'm not sure what's reasonable degree.
The -- the LI-RADS specifically is designed to take away at least some of the subjectivity from conversation between radiologists and clinicians, and there are a lot of studies that are performed to validate LI-RADS and LI-RADS works.
And the probabilities that I'm citing to you have been validated in multiple studies. So when I say something meets criteria for LI-RADS 3, that communicates that that probability of HCC is about 33 percent.
BY ATTORNEY VAUGHN:
Q. You -- I'm sorry.

Page 84

A. So, hence -- hence, the patient should be followed every three to six months.
Q. The opinions stated in your expert report, did you give them to a reasonable degree of medical certainty?
A. I'm sorry. Can you repeat that again?
Q. The expert opinions within your report, did you give them to a reasonable degree of medical certainty?
A. I'm not -- I'm not sure what you're exactly asking me. I provided my opinion based on my medical training and my years of practice and my expertise in LI-RADS, so this is how I interpret the imaging.
Q. And can you say to a reasonable degree of medical certainty as of 2016 that Mr. Roberts had cancer?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Mr. Roberts had three lesions. Each one of

Page 85

them met criteria for LI-RADS 3 observation. LI-RADS 3 observation has 33 percent of probability of being malignant.
I have no tools to stratify that probability. Nobody has those tools. Those tools yet do not exist.
BY ATTORNEY VAUGHN:
Q. Your next sentence, you say: When they are followed long term, up to 60 percent of LR-3 observations progress to HCC within 48 months.
Did I read that right?
A. Yes.
Q. Why did you choose 48 months?
A. That is the study that I quoted followed the lesions up to 48 months. That's the number that they've -- they've reported.
Q. And how long was between Mr. Roberts' 2016 scan and 2018 scan?
A. Two years and I think --

Page 86

May, June -- four months. Two years and four months, about.
Q. And you cited -- you cited two studies for this one, didn't you?
A. I have -- no, for that statement, it was 18.
Q. 18? Is there two citations here in 18? Did you cite to yourself as well?
A. That is a statement about -- that is a statement about the 33 percent being malignant.
Q. Well, that 33 percent malignant, you cite as 17. 18, you cited two different sources. Right?
A. The statement for 48 months is Kim YY, et al, for 18.
Q. Do you know why there's a second citation on this one?
A. It may have been inadvertently pasted there.
Q. Okay.
A. Again, that citation is a general citation of LI-RADS --

Page 87

Q. Uh-hum.
A. -- its application, its concepts, how it applies. This is the -- the release of version 2018, that's the citation.
Q. How did you choose this Kim article?
A. Because that Kim article specifically looked at outcomes of LI-RADS 3 and LI-RADS 4 observation. This is the paper that looked at the longest follow-up, 48 months. This is the paper that I cite in my -- in my papers, in my -- when I talk about -- give lectures, this is the paper that I cite.
Q. Oh, so you were familiar with this paper prior to writing your expert report?
A. Yes.
Q. Does this paper give time points before 48 months?
A. Yes.
Q. Does this paper give time

Page 88

points closer to what would be relevant in this case, which is, what you said, two years and about four months?
A. Yes.
ATTORNEY ROSE: Object to the form.
BY ATTORNEY VAUGHN:
Q. And what percent increase -- scratch that.
What percent of LR-3s go on to be HCC within the relevant timeframe, approximately two years?
ATTORNEY ROSE: Object to the form.
THE WITNESS: May I reference the graph so --
ATTORNEY VAUGHN: You may.
THE WITNESS: Thank you.
ATTORNEY VAUGHN: Can we go ahead and drop that one in, Kathryn? I believe it's 2020 MRI LI-RADS.
THE WITNESS: About 20 percent.

Page 89

BY ATTORNEY VAUGHN:
Q. About 20 percent. And so that would be the case for Mr. Roberts? It would be just about 20 percent chance that his LR-3 would have progressed to HCC at the time they caught it?
ATTORNEY ROSE: Object to the form.
THE WITNESS: About 20 percent of all LI-RADS 3s progress to HCC by about 48 months -- I mean -- sorry -- 24 months, 24 months.
BY ATTORNEY VAUGHN:
Q. And you didn't put that in your expert report, did you, that there would only have been a 20 percent chance for him?
ATTORNEY ROSE: Object to form.
THE WITNESS: I cited the -- I cited the reference there, that long-term follow-up results -- that a substantial proportion of

these will eventually end up being cancerous.

- - -

(Deposition Exhibit No. Chernyak-5, 2020 Article by Kim, et al, "MRI Ancillary Features for LI-RADS Category 3 and 4 Observations: Improved Categorization to Indicate the Risk of Hepatic Malignancy", was marked for identification.)

- - -

BY ATTORNEY VAUGHN:

Q. At the time frame for Mr. Roberts, it would have only been a 20 percent chance; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: It's not 20 percent chance. It's 20 percent of all LI-RADS 3s progress.

BY ATTORNEY VAUGHN:

Q. And all LI-RADS 3s would include LI-RADS 3s that have a viral

etiology; correct?

A. Yes, all LI-RADS 3s -- all LI-RADS 3s within LI-RADS population.

Q. Are those with a viral etiology more likely to go on to develop HCC than those without a viral etiology?

A. I have no data to support that statement.

Q. Have you done any research into that?

A. Into?

Q. Have you done any research to see if viral -- scratch that.

Have you done any research to see if those with LI-RADS 3s that have a viral etiology are more likely to go on to develop HCC than those with LI-RADS 3s without a viral etiology?

A. I personally have not done this research.

Q. Do you remember at the end of your expert report when you said there was an MRI done in 2016 that was incorrect?

ATTORNEY ROSE: Object to the form.

THE WITNESS: At the end of the report, there was a -- it was a mistake, MRI of 2 -- can you go back to the report?

ATTORNEY VAUGHN: Right here (Indicating).

THE WITNESS: Yes.

BY ATTORNEY VAUGHN:

Q. And there was no MRI done in 2016. Right?

A. It was supposed --

ATTORNEY ROSE: Object to the form.

THE WITNESS: It was supposed to be April 2016 CT.

ATTORNEY VAUGHN: You know what? I pulled up the wrong one. Give me one second. Kathryn probably dropped the right one.

Sorry. This is the one I meant to pull up.

BY ATTORNEY VAUGHN:

Q. And this is what you cite, correct, this 2020 paper by Kim?

A. Uh-hum --

Q. MRI --

ATTORNEY ROSE: I'm sorry. Mr. Vaughn?

ATTORNEY VAUGHN: Yeah?

ATTORNEY ROSE: I'm sorry. I just want to make sure I have what you're looking at. This is Exhibit 5?

ATTORNEY AVILA: Yes, this is Exhibit 5.

ATTORNEY ROSE: Doctor, so you know, Exhibit 5 is available to you in the --

ATTORNEY VAUGHN: Feel free to download it and look it all over. Take your time with it.

ATTORNEY ROSE: And the study that you had up on the screen earlier --

ATTORNEY VAUGHN: We haven't dropped it yet. I opened up the

Page 94

wrong PDF. That was my fault.
ATTORNEY ROSE: Oh, okay.
You didn't intend to introduce that as an exhibit; correct?
ATTORNEY VAUGHN: No, yeah, that was my fault.
ATTORNEY ROSE: Thank you for the clarification.
BY ATTORNEY VAUGHN:
Q. All right, Doctor. And this study was done on those with an MRI; correct?
A. Yes.
Q. And there was not an MRI done on Mr. Roberts in 2016, was there?
A. Correct.
Q. On page 2, do you see where they say: The progression of malignancy is greater in untreated LR-4 observations than untreated LR-3 observations?
A. Yes.
Q. Do you agree with that?
A. Yes.
Q. And this was a retrospective

Page 95

study. You don't have any problems using retrospective studies, do you?
A. I do not.
Q. Do you have any critiques of people using retrospective studies as an expert?
ATTORNEY ROSE: Object to the form and outside the scope.
THE WITNESS: Do I answer?
ATTORNEY ROSE: Yes, please.
THE WITNESS: Retrospective studies have well-established limitations; however, vast majority -- not vast, but majority of the data that we have for clinical research is retrospective, just by nature of the beast.
BY ATTORNEY VAUGHN:
Q. Understood.
What patient population was this study done in; do you recall?
A. No. I would have to go back and look.

Page 96

Q. That's fine. I can take you to it.
On the third page, in the results section, actually, do you see where it says: 57, which is 73 percent of the patients, had a hep B virus infection?
A. Uh-hum, is it -- liver cirrhosis or chronic hep B, yeah.
Q. So three-fourths of the patient population here had hep B; correct?
A. Uh-hum.
Q. And you don't know if Mr. Roberts had hep B, do you?
A. But the next statement is: 85 percent have liver cirrhosis, in that -- in this study.
Q. Does liver cirrhosis progress differently in those with a viral etiology versus those without a viral etiology? Or is that outside your expertise?
ATTORNEY ROSE: Object to

Page 97

the form.
THE WITNESS: That is outside of my expertise.
BY ATTORNEY VAUGHN:
Q. And so you wouldn't know if it's proper to apply a study where the patients had hep B cirrhosis to a person who does not have hep B; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: LI-RADS population -- if you would like to pull up the study that you've just referenced and showed, LI-RADS population is patients who have cirrhosis and those who have hepatitis B infection with or without cirrhosis and patients who have personal history of HCC.
LI-RADS does not differentiate between these patients, meaning that the LI-RADS criteria are all applicable equally to any person who falls

Page 98

into the criteria of LI-RADS population.
BY ATTORNEY VAUGHN:
Q. Well, now, you say LI-RADS is applicable to each person equally. You don't actually know that yet. Right? It just applies it equally to each type of person. Right?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Can you please specify what you're asking me?
BY ATTORNEY VAUGHN:
Q. A LI-RADS 3 automatically applies the same way to any patient, regardless if they have a viral etiology or don't have a viral etiology; correct?
A. Correct.
Q. I'm on page 7 of this study. The bottom left-hand corner, it says: Observations with HBP -- what is HBP?
A. Hepatobiliary phase.
Q. And which phase is that? There's three phases, right -- oh, this

Page 99

is an MRI, so this wouldn't have been done in a CT, would it?
A. This is MRI and this is MRI done with a very specific contrast agent that this -- that Mr. Roberts did not have this MRI.
Q. And it says: Isointensity showed a considerably lower risk of progression to LR-5 from LR-3 observations.
What is an LR-5 observation?
A. LI-RADS 5 observation definite HCC has about 95 percent probability of being HCC, about 99 probability of being malignant.
Q. So is this talking about going from an LR-3 to HCC?
A. Yes.
Q. And you're saying those with isointensity have a low risk of progression?
A. Have lower risk based on the study.
Q. And earlier were you telling

Page 100

me that Mr. Roberts had isointensity?
A. No. Again, this -- Mr. Roberts never had MRI with hepatobiliary phrase.
Q. But you think this study still applies to Mr. Roberts even though he didn't have an MRI like it said he did in your expert report in 2016?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Also, the sentence you're highlighting talks about a different study. It says: Similarly, a prior study including a large proportion of observation with hepatogram.
So it's -- the sentence you're highlighting references a prior study, but again, you know, there are studies that look into trying to figure out how we can risk stratify LR-3 and LR-4 observations.
Again, there's no consistent

Page 101

results and there's no consistent way in which we can say this lesion will progress and this lesion will not, and that's why it's a considerable interest to researchers and NIH particularly to create such models, but such models do not exist.
BY ATTORNEY VAUGHN:
Q. And of all the studies that you could have cited, this is the one you decide to cite. Right?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Yes, because this study has the longest LR-3 follow-up.
BY ATTORNEY VAUGHN:
Q. The risk of malignancy in untreated final LR-3 observations seemed low?
A. Low enough to warrant routine surveillance.
Q. What does that mean?

Page 102

A. That patients with LR-3 observations need to be surveilled. You don't need to treat them right away, but you do need to follow them.

It says: low enough to warrant routine surveillance.

Q. And did you review the major limitations of this study?

A. Yes.

Q. And you realize that one of the limitations, again, of this study is not only is a single-center study, but the majority of patients have the hep B virus, which may limit the generalizability of our results?

A. Generalizability, yes.

Q. What does that mean?

A. These are standard limitations which are applicable to retrospective studies, because you work with sample that you have. The study was -- happened to be in the population that has majority of patients who had hepatitis B infection.

Page 103

In this case -- in this case, actually, this is a comparable study because 85 percent of these patients had HCC.

Q. Are the study authors warning against using their results in patients without hep B?

A. No. They just --

ATTORNEY ROSE: Object to form.

THE WITNESS: It's a standard acknowledgment of caution that if you open up any studies, it discusses limitations, because every studies -- every study has limitations, even prospective, randomized, controlled.

You know, any study you find, the next to the last paragraph will say, our study has limitations, because that's -- unfortunately, every study has limitations. Nothing's perfect.

BY ATTORNEY VAUGHN:

Page 104

Q. Did you apply caution when applying this study to this case?

A. I did not just -- this study was used to show the long-term, you know, outcomes. The results in these studies are repeated in -- are supported by other studies. This one just happens to be the longest one, which is -- that's why I -- I tend to cite it.

The opinions that I've provided are based on meta-analyses, which again, do not distinguish between patients who have cirrhosis versus patients who have hepatitis B infection versus those who have personal history of HCC.

Q. And as you testified earlier, you weren't aware of the patient population in this study when you were doing your expert report, correct, that they were hep B patients?

ATTORNEY ROSE: Object to the form.

THE WITNESS: I -- I don't

Page 105

-- I'm not sure why this is relevant.

This patient -- this study is applicable to patients -- this study uses patients who have fallen into LI-RADS population. LI-RADS applies to all patients within the LI-RADS population equally. There's no caution, limitation, or restrictions to how we apply results like this.

BY ATTORNEY VAUGHN:

Q. And you didn't cite to a study where the patient population was not hep B; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: The study that I cited, the Lee, et al, has all kinds of patient populations.

BY ATTORNEY VAUGHN:

Q. I'm sorry. I'm talking about citation 8, Kim -- let me go back here.

Page 106

So when you said: When followed long term, up to 60 percent of LR-3 observations progress to HCC within 48 months --

A. Yes.

Q. -- you cited to Kim --

A. Yes.

Q. -- which is the hep B study we just went over, and then you cited to yourself and said that that was a miss-cite. So the only one you cited to was a hep B study; correct?

A. For this particular statement, yes.

Q. And in that statement, you were talking about 48 months, even though our client developed cancer within 28 months?

ATTORNEY ROSE: Object to the form.

THE WITNESS: I was providing the context of what LI-RADS 3 means, is, and why it requires follow-up.

Page 107

BY ATTORNEY VAUGHN:

Q. Do you have a 2023 publication regarding looking back on LI-RADS? Do you recall that publication?

A. Can you be more specific? I have a bunch of them.

ATTORNEY VAUGHN: Yeah. Kathryn, can you drop in the 2023 LI-RADS looking back?

ATTORNEY AVILA: Okay. This is Exhibit 6.

- - -

(Deposition Exhibit No. Chernyak-6, 2023 Article by Chernyak, et al, "LI-RADS: Looking Back, Looking Forward", was marked for identification.)

- - -

BY ATTORNEY VAUGHN:

Q. Doctor, do you recall this paper that you published?

A. Uh-hum. Yes.

Q. And you're the lead author on this; correct?

Page 108

A. Yes, sir.

Q. And it's a 2023 publication?

A. Yes, sir.

Q. And you didn't cite this in your expert report, did you?

A. No.

Q. And so did LI-RADS initially come out in 2011?

A. Yes.

Q. And it says it has evolved and expanded in scope.

A. Yes.

Q. Can you explain that?

A. LI-RADS initially was developed as a diagnostic scale. Since then, it includes the surveillance algorithm that allows -- it's applied for surveillance. It also includes a diagnostic algorithm that's applicable to contrast enhanced ultrasound. It also includes posttreatment assessment algorithms. It includes lexicon...

Q. Why has it evolved over time?

Page 109

A. Because the evidence was accumulating and you can't start with everything all at once, so we started with something that was doable in 2011 and as that solidified, expanded to cover other areas of HCC surveillance, diagnosis, and posttreatment assessment.

Q. And is LI-RADS still evolving?

A. Yeah. Yes.

Q. And it notes here that the authors discuss the current gaps of knowledge -- gaps in knowledge?

A. Yes.

Q. And were you one of those authors that was discussing the knowledge gaps regarding LI-RADS?

A. Yes.

Q. Can you go over those knowledge gaps with us, if you recall?

A. Do you want me to go into very detail?

Q. Yes.

A. So in -- let's see -- in --

Page 110

you know, there are challenges in HCC surveillance, primarily because ultrasound is a very subjective modality based on the way it's performed. It's everywhere.

And at the time that this paper came out in 2023, the visualization scores, which is the assessment of how diagnostic or how clear the liver is visualized on ultrasound, at the time, the visualization scores were not yet incorporated into management and assessment schema.

Since then, in 2024, an updated ultrasound surveillance came out that addressed that gap.

The next gap is diagnostic population. Right now, the diagnostic population is very restrictive, means that we only can apply LI-RADS to patients who have cirrhosis, who have hepatitis B infection with or without cirrhosis, or patients who have personal history of HCC.

Page 111

We do know that this is very restrictive, because patients who have, for example, advanced fibrosis and have underlying MASLD or hepatitis C infection and have an advanced fibrosis, such patients are, too, at higher risk of HCC.

Right now, we cannot use LI-RADS criteria to diagnose the HCC noninvasively in such patients and we're proposing that potentially there some can be imaging biomarkers, including elastography values or some, you know, blood biomarkers that eventually may help us to expand patient population, but at this point, it is not yet so.

LI-RADS is complex. We have a decision tree. We have a -- a lot of rules and regulations. Sometimes users express that this is a very complex system. Unfortunately, it is complex because the nature of HCC diagnosis is quite complex.

In the next release of LI-RADS, we're trying to simplify it as

Page 112

much as we can; however, there's only so much that you can do because, again, the diagnosis of HCC is a complex matter as it is.

The next question -- next gap is the application of ancillary features. Ancillary features are -- in the current version of LI-RADS diagnostic algorithm, we have many of them; however, we have now accumulated sufficient data to narrow that. We probably don't need all of them and we can decrease this number and we're planning to do that in the next release.

The next, limited sensitivity of LI-RADS 5 or HCC, because we have very stringent criteria, very demanding criteria, to ensure that when we say something is LI-RADS 5 that it is indeed LI-RADS 5, that means that we maximize specificity of the diagnosis.

It is a general statement for any test that if you maximize specificity, you sacrifice sensitivity,

Page 113

meaning that if I say that LI-RADS 5 is HCC, I am 95 percent probability that something is HCC; however, only about half to two-thirds of HCCs meet criteria for LI-RADS 5.

So that's another gap that we discussed that it would be great if we could improve the sensitivity for LI-RADS 5 without sacrificing specificity. There are certain things that we may consider, but we do not yet know if we have enough data to support these, so that may or may not be applicable.

Challenges of indeterminate observation is what I've discussed with you, is that we have LI-RADS 3 observations that are -- that we stop following them. Some of them progress, some of them don't, but we just don't know which one, so we cannot identify exactly what -- what can be followed less aggressively or not -- or more aggressively, so that's a major challenge, as I've discussed before.

Page 114

LI-RADS M is less of a challenge. LI-RADS M means malignant, but not HCC specific. Right now, LR-M observations have to be biopsied even though about a third of them end up being HCC.

So there's a desire to create some sort of criteria to recover some of these HCCs back into LI-RADS category. Probably we do not have yet data, again, to identify these HCCs with high enough specificity.

LI-RADS 4 is a lessor challenge but because in -- it has about 60 to 70 percent probability of being HCC, so depending on the context, sometimes these patients get a biopsy, sometimes these patients get just treatment with presumptive diagnosis of HCC, sometimes these patients get a follow-up.

So there's, again, some uncertainty there that would be great if we could have some data to guide the

Page 115

management in more consistent manner, so that's the challenge that we discuss there.

What else? What other challenges? Challenges in reporting, again, there are certain requirements that -- that unfortunately in a very busy practice, people may not necessarily adhere to.

So we are working on figuring out how to make reporting challenging -- less challenging, including automatic reporting, including natural language processing things, providing templates for people to use.

There are also now work on providing standardized templates for treatment, for, like -- for IR -- for interventional radiology to do so that we can easier correlate for posttreatment assessment, so that's reporting issues.

Treatment response algorithm, the challenges that we discuss here have been addressed, because a

Page 116

recent release has happened last year. So last year, we have a treatment response algorithm that came out that addressed some of the challenges we showed here, including incorporation of ancillary features including separating the treatment response assessment based on radiation versus nonradiation treatment.

Do you want me to go on to future directions?

Q. Please.

A. So with future directions, of course, this is, you know, very nebulous, we hope things will, you know, happen the way we hope, but may not, our most important thing is incorporating of AI into some of the assessments to decrease some of the subjectivity that is inherent right now in qualitative assessment.

If you look at page 12 of this paper, you will see this is the grand vision -- this is the grand vision

Page 117

of something that we hope that will happen eventually. This is probably 10 to 20 years from now, where we will have some sort of AI model that will incorporate a lot of information, including imaging modality that we have, including the features that are pertaining to each particular observation, including features that are pertaining to the liver and to the patient, including incorporating patient factors, including all of these genetics, including all of these things, and then providing a much more precise probability, so instead of saying, you know, Mr. -- you know, patient X has LI-RADS 3, which is 33 percent probability, it would say something like, this patient has, I don't know, 52.3 percent probability of having HCC and his -- you know, this lesion has 92 percent probability of responding to treatment X.

That is all theoretical and really a desired hope. A lot of -- a lot

Page 118

of this will need computation power we don't have, AI models we don't have. It requires us to create a large amount of institutionalized registries, which is proving to be very challenging.

So this vision is unlikely to implement itself in the next five years, hopefully in ten years. But -- maybe I'm wrong, maybe, you know, a breakthrough in some technology will happen and it will be -- happen even earlier.

Q. So as you were saying, the authors, which is you, envision LI-RADS to eventually transform and will integrate patient characteristics; correct?

A. Eventually. Again --

Q. Sorry.

A. Eventually, hopefully next -- many, many years.

Q. Hopefully it does eventually. Right?

A. Hopefully eventually.

Page 119

Q. At this time, though, it does not consider patient characteristics.

A. Correct.

Q. And as you pointed me out to page 12, patient factors that it is not considering would be things like age, sex, race, genetics, viruses -- would that be like if they had a hep B virus --

A. Hep B --

ATTORNEY ROSE: Form.

BY ATTORNEY VAUGHN:

Q. -- biomarkers and circulating tumor DNA. Currently, it is not -- LI-RADS is not looking at the patient factors; correct?

A. Correct.

Q. And in addition, you did not look at Mr. Roberts' medical records to identify all of his specific patient factors; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: Correct.

Page 120

BY ATTORNEY VAUGHN:

Q. I think earlier you testified that you have to have certain risk factors for LI-RADS to apply; is that correct?

A. Yes.

Q. What risk factor does Mr. Roberts have that allows you to apply LI-RADS?

A. He has imaging features of cirrhosis.

Q. And if he did not have cirrhosis, you could not apply LI-RADS; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: Patients who do not have cirrhosis or viral hepatitis or personal history of HCC, LI-RADS, we cannot apply.

BY ATTORNEY VAUGHN:

Q. And so if Mr. Roberts did not have cirrhosis or hepatitis or a history of HCC, you could not apply

Page 121

LI-RADS; correct?

A. A patient without risk factors, without precise -- who does not fall into LI-RADS definition of LI-RADS population, LI-RADS is not applicable.

Q. And here on page 4, it says: Therefore, research is needed to divine the conditional probabilities of HCC based on age, sex, etiology, and severity of liver disease and possibly other factors, such as quantitative imaging and circulating biomarkers.

Is that talking about what we were just talking about, things that they're hoping LI-RADS does in the future?

A. Yes.

Q. And why would they want LI-RADS to be considering patient age?

ATTORNEY ROSE: Object to the form.

THE WITNESS: These are all theoretical things that we think eventually may, you know -- to

Page 122

provide that precise probability, eventually we hope that that will somehow contribute to calculation of the risk, you know, that you have these imaging features in this particular-looking liver, in this particular patient. All of that, AI would take and do some, you know, black box calculation -- or not black box calculation -- and spit out a number.

These are -- these are our theoretical thoughts of what could go into calculation of conditional probability of HCC.

BY ATTORNEY VAUGHN:

Q. And so currently, LI-RADS cannot give a precise probability for an individual patient on their LI-RADS 3 being an HCC; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: No. We're talking here about conditional

Page 123

probability.

BY ATTORNEY VAUGHN:

Q. And you're saying eventually you're hoping AI considers all these patient-specific factors. Right now, it is the treating physician that considers all the patient-specific factors; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: No, because right now, we -- we have a well-established probability that works -- right, if we take all LI-RADS 3 observations everywhere across the world and have a magic wand and right now we will know exactly precisely what each and every one of those things is, about 33 percent of all LI-RADS observations in the world will be -- will be HCC.

BY ATTORNEY VAUGHN:

Q. And that's counting the

Page 124

people that have viral etiologies; correct?

A. That is anybody who falls into LI-RADS population.

So what we are hoping, what our future vision is, but we're nowhere near this, is instead of saying that patient has -- patient X has 33 percent -- you know, has LI-RADS 3 and that means that his probability of HCC is 33 percent, that that number would be edited based on all kinds of different things that we may not even can see right now, texture analysis, we don't know any of that yet.

So that's our hope because then we can't -- we would be able to say, okay, this patient -- these patients' lesion needs to be -- have more attention or less attention. We do not have that right now.

Right now, if you have LI-RADS 3 observation, the recommendation is for the patient -- for that lesion to

Page 125

be followed every three to six months.

Q. And your hope or your goal is for LI-RADS to be more accurate in the future; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: Our hope and goal eventually to provide more precise probability of patient-specific probability.

BY ATTORNEY VAUGHN:

Q. Looking at page 5 of your study, it notes: The granularity of LI-RADS burdens radiologists more than systems that classify observations dichotomously as definitive HCC versus not.

Can you explain what that means?

A. Certainly. So most other diagnostic system only provide diagnostic criteria for lesions that meet criteria for HCC. So what we -- what we provide for LI-RADS 5, they provide for something

Page 126

that they call definite HCC or whatever diagnostically -- whatever the criteria they perform.

They do not provide any criteria for anything that doesn't meet the LI-RADS 5 criteria -- LI-RADS 5 criteria. Right?

So then everything else is left up to a radiologist's discretion to define, to describe. So there's an enormous amount of inconsistencies or interreader variability in terms of opinions.

So LI-RADS takes that -- or minimize -- or decreases that so that, you know, if I look at this lesion and I apply LI-RADS criteria, I provide the category LR-3, as opposed to this patient was -- you know, was -- let's say, used, you know, former, you know, EASL criteria, it would just be called indeterminate and there would be no way to say, you know, what the probability of anything is and how this lesion should be

Page 127

treated.

Does that -- does that make sense? Should I -- should I clarify that in any way?

Q. If you feel like you need to clarify it, feel free.

A. Only -- only if it's not clear.

Q. LI-RADS is the only system that gives a probability of it being HCC; correct?

ATTORNEY ROSE: Object to form.

THE WITNESS: LI-RADS -- LI-RADS is the only system that provides risk stratification based on probabilities for categories.

BY ATTORNEY VAUGHN:

Q. All other systems are, do you have HCC or do you not have HCC; correct?

A. Correct.

Q. How many other systems are there besides LI-RADS?

Page 128

A. Well, it's decreasing, because in United States, there's no other system, because LI-RADS was adopted in AASLD in 2018 and UNOS, which is the system for liver transplantation allocation graft, they've adopted LI-RADS criteria as of 2023, I believe -- '23 or '24. I think -- it is I think '23, but I would have to get the precise date -- and as of January of this year, so January of 2025, the EASL criteria, which is European criteria for HCC, have adopted LI-RADS.

So as of right now, LI-RADS is a unified imaging criteria used for assessment of liver in high-risk patients in North America, Europe. Either all or parts of LI-RADS are used in South America either as is or adopted into their specific -- you know, country-specific guidelines.

The Korean KCL criteria, they've adopted LI-RADS lexicon. They're a definite HCC -- so there -- there --

Page 129

the Western criteria are basically harmonized. Every -- you know, most of the countries adopted LI-RADS.

The Eastern criteria are a little tricky because they have different treatment paradigm for their patients and therefore they -- they are interested in maximizing sensitivity of HCC diagnosis as opposed to Western guidelines which maximize specificity.

So the Eastern guidelines, including the Korean and APASL criteria, which is Asian Pacific Study for Liver Disease, they -- they have cited different criteria expanding so that they improve sensitivity by -- you know, at the expense of specificity.

So -- does that make -- did I answer your question?

Q. Do you know why the Eastern civilians are more concerned with the specificity than the Western civilizations?

ATTORNEY ROSE: Object to

Page 130

the form.
THE WITNESS: It's the other way around. Because they have different patient population and they treat patients differently than we do --
BY ATTORNEY VAUGHN:
Q. What's different -- sorry.
A. Our -- we -- our Western populations have a higher proportion of patients with cirrhosis, where resection is not always a possibility because of liver reserve, and the -- really the goal or the best treatment that we can offer patients is liver transplantation.
And as you can imagine, you know, there's only so many liver organs that are available, so when we prioritize somebody to receive a liver organ, we want to make sure that we are prioritizing patients who truly have HCC.
So that's why we maximize specificity, meaning that when I say somebody has LR-5, it is almost -- it's

Page 131

as good as biopsy that this is indeed an HCC.
In Asia, where the proportion of -- of hepatitis B patients is much higher and a lot of them have preserved liver function, they -- they more often are treated with resection, so they can afford to be less specific, but more sensitive because they were -- they're able to treat their patients in a different manner that we can't.
Q. And so the Asian populations have higher rates of hep B than Western civilization?
A. Yes.
Q. And so they want their LI-RADS different because their patients have hep B; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: No. They have patient -- they have -- their patients -- they have patients who because hepatitis B virus is

Page 132

tumorigenic, means that it can cause HCC without going through the process of cirrhosis, that means that they have higher proportion of patients who have HCC without actually having cirrhosis, that means that they are able to offer resection to these patients because their liver is not -- they have substantial liver reserve, meaning that you can lose part of the liver and still survive and have reasonable liver function.
Patients with cirrhosis, their liver function may be such that they don't have livers or meaning that if they lose half of their liver, they won't be able to function -- the liver won't be able to function.
So there's different patient populations, different paradigms.
BY ATTORNEY VAUGHN:

Page 133

Q. So you agree that those with hep B are at higher risk of HCC than those without hep B?
A. No, that's not why I'm saying.
Q. Do you agree with the statement I just made?
A. I disagree with --
ATTORNEY ROSE: Object to the form.
BY ATTORNEY VAUGHN:
Q. You don't believe that those with hep B are more likely to develop HCC than those without hep B?
A. That statement is correct, that patients who have hepatitis B of course have higher risk of development of HCC than patients who don't have HCC -- I'm sorry -- who don't have hepatitis B.
Q. And those with a LI-RADS 3 that have hepatitis B are more likely to progress to HCC than those without hep B; correct?
ATTORNEY ROSE: Object to

Page 134

the form.
THE WITNESS: I do not have scientific evidence that -- I don't have -- I am not aware of any study that looked at LI-RADS 3 progression in the setting of cirrhosis but no hepatitis B versus progression of LR-3s in the setting of hepatitis B without cirrhosis.
There's no study based on my knowledge that looked at this particular question, so I have no scientific evidence to compare the rates of progression in patients who have cirrhosis versus patients who just have hepatitis B.
ATTORNEY ROSE: Brett, we've been going for about an hour. I just wanted to flag that, if you have a good stopping point.
ATTORNEY VAUGHN: Do you mind if I get through this study, Doctor, or do you want to take a

Page 135

break right now? I'm fine either way.
THE WITNESS: Can you be off the record for a second?
ATTORNEY VAUGHN: Say again?
THE WITNESS: Can you be off the record for a second?
ATTORNEY VAUGHN: We can take a break. Let's go ahead and take a break.
THE WITNESS: I just need to use the restroom.
ATTORNEY VAUGHN: Absolutely.
THE VIDEO TECHNICIAN: Off the record, 11:13.
- - -
(A discussion off the record occurred.)
- - -
(A recess was taken from 11:14 a.m. to 11:30 a.m.)
THE VIDEO TECHNICIAN: We are back on the record at 11:30

Page 136

a.m.
BY ATTORNEY VAUGHN:
Q. Earlier, Doctor, you were testifying about ancillary factors? Do you recall if Mr. Roberts had any ancillary factors in his 2016 scans?
ATTORNEY ROSE: Object to the form.
ATTORNEY VAUGHN: Sorry. Let me rephrase that. I said factor. I believe it was ancillary features.
THE WITNESS: Yes.
BY ATTORNEY VAUGHN:
Q. Did Mr. Roberts have any ancillary features in his 2016 scan?
A. No.
Q. And do ancillary features -- scratch that.
If ancillary features are present, is it more likely to be HCC?
ATTORNEY ROSE: Object to the form.
THE WITNESS: It depends

Page 137

what features.
BY ATTORNEY VAUGHN:
Q. Which ancillary features would make it more likely to be HCC?
ATTORNEY ROSE: Object to the form.
THE WITNESS: There are ancillary features favoring malignancy in general. There are ancillary features that favor HCC specifically, and there are ancillary features of benignity.
Ancillary features that favor HCC specifically are nodule -- nodular appearance, mosaic appearance, nonenhancing capsule and -- am I too fast, Kim? It's okay? You good? Okay. Sorry -- and blood products in mass, also fat in mass, so these are fairly specific for HCC, although recent data, again, demonstrates that these present very uncommonly in clinical practice. Even though

Page 138

they're quite specific for HCC, they are very -- we -- we see them uncommonly.
BY ATTORNEY VAUGHN:
Q. And you didn't see any of the ancillary features supporting HCC in Mr. Roberts' 2016 imaging; correct?
A. There were no ancillary features present, and because -- had they -- you know, so if ancillary features are present, we increase the category.
So if either of them were present, then I would -- I would have said that these are LR-4 observation, not LR-3.
Q. And if the same workup was in LR-2, the ancillary feature would bump it up to an LR-3 or would it bump it all the way to LR-4?
A. No, you can only bump up one category.
Q. So you can have ancillary features and still be an LR-3?
A. Yes. Ancillary feature

Page 139

application is not mandatory, so it is -- it is left to the interpreting radiologist whether or not they want to apply ancillary features assigning the final category.
There are rules about how to apply them, but you're not -- you're not required to apply them.
Q. I'm going to go back to the study that we were previously on, your 2023 LI-RADS study. I'm on page 8 and I'm at the paragraph --
A. Exhibit 6?
Q. What was that?
A. Exhibit 6?
Q. I believe it was Exhibit 6, the most recent one we've admitted.
A. Page?
Q. Page 8, and I'm on the section where it starts in bold: Challenges of Intermediate Observations. And intermediate observations, that's an LR-3; correct?
ATTORNEY ROSE: Object to

Page 140

the form. I think you read the document incorrectly, Brett.
ATTORNEY VAUGHN: Challenges of -- I did that the other day, too. Thanks, Nina.
Challenges of indeterminate observations, is that an LR-3?
THE WITNESS: For the purposes of this particular text, you can see that the indeterminate is placed in quotations, and this entire paragraph discusses the observation -- the challenges that we see with LR-3, 4, and M category.
BY ATTORNEY VAUGHN:
Q. So LR-3, LR-4, and LR-M are all indeterminate observations?
A. They are indeterminate for the purposes of this application.
Q. What do you mean by that?
A. This is not the term that's used in LI-RADS. This is just a section header kind of putting them together so

Page 141

we can discuss these challenges with these categories in one section.
As you can see, the way that the paper is structured, that every paragraph has its own kind of header unifying the theme of the paragraph, so that's what we call it. The indeterminate observation is not a LI-RADS-specific or defined term.
Q. Gotcha. But in your own publication, you call an LR-3 indeterminate; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: No, we did not. We said -- we -- we use this as a header to discuss the challenges with LR-3, 4, and M category; but if go and start reading the text, it's either LR-3 or LR-3 means intermediate probability of malignancy.
So --
BY ATTORNEY VAUGHN:

Page 142

Q. Is it intermediate or indeterminate?
A. LR-3 means intermediate probability of malignancy.
Q. What does this mean, challenges of indeterminate observations, in your study that you published?
A. So challenges that are -- we face with LR-3, 4, and M categories, where, again, for LR-3 category, as we've discussed, the challenges is that right now, we have no way to risk stratify them and the probability of HCC and malignancy in these observations is now -- is not low enough where we can say forget about them and patient just can go back to routine surveillance, and it's not high enough where we can say patient needs to be biopsied or treated. Right?
So we're struck with these observations. We know some of them will progress. We know some of them will not. We just don't have a good way of saying which one, so then we're stuck.

Page 143

We're saying every person who has LR-3 observation has to have three- to six-month follow-up and as I mentioned before, this of course produces quite a bit of a healthcare burden, so therefore this is a challenge recognized by us, recognized by NIH.
Unfortunately, this challenge is -- as of 2025 is unsolved, so right now, we still have to follow LR-3 observations every three to six months.
ATTORNEY VAUGHN: Is that your dog snoring in the background?
THE WITNESS: Yes. I'm really sorry. Should I kick her out? Let me wake her up.
(Pause.)
THE WITNESS: I changed -- I'm really sorry. I changed her position.
ATTORNEY VAUGHN: You're okay.

Page 144

THE WITNESS: Sorry about that.
BY ATTORNEY VAUGHN:
Q. So when it's talking about these challenges, is this one of them, an additional complication that LR-3 and LR-4 observations have variable natural history?
A. Yes.
Q. And can you explain that sentence for me?
A. Again, if we take all LR-3 observations and follow them, some of them will progress to HCC fairly quickly. Some of them will progress to HCC very slowly. Some of them will be unchanged. Some of them will resolve.
So, again, we don't have a good model that identifies those LR-3s which will end up progressing to HCC.
Q. And what does the word "variable natural histories" mean?
A. Just what it says. Natural history means if you just let it go

Page 145

without treating, like, what will happen to it, that's what natural history means. Variable means some progress quickly, some don't progress, some regress, some stay the same.
Q. And then in your study, you noted that several studies found that all LR-3 observations 23 to 60 percent, remained LR-3; is that correct?
A. Yes.
Q. And do you stand by that?
A. That is not my cite. These are the citations that I provide.
Q. And you found in your study that this is worth citing to and discussing; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: This is not a -- this paper that you're referring is not a study. It's a review paper.
BY ATTORNEY VAUGHN:
Q. So your publication, your

Page 146

review paper, you noted that several studies found that all LR-3 observations, 23 to 60 percent remained LR-3; correct?
A. Yes.
Q. And that's what Mr. Roberts had -- that you say Mr. Roberts had, was an LR-3; correct?
A. Yes.
Q. And so in your opinion, did Mr. Roberts have a 23 to 60 percent chance of that LR-3 remaining as an LR-3?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Based on the evidence that we have, he had 23 to 60 percent chance that it would remain, 7 to 24 percent chance of progression.
You can -- you can see how these numbers are very, very -- the ranges are big and that underscores the challenges, that we don't have a good sense of which of the LR-3 observations

Page 147

will stay the same, progress, or change. We just don't know.
That's why we have to follow them.
BY ATTORNEY VAUGHN:
Q. Is LR-3 kind of just guesswork?
ATTORNEY ROSE: Object to the form.
THE WITNESS: It is a collection of observations that imaging features are such that the probability of HCC at that particular moment is 33 percent.
So it's not low enough to say forget about it. It's not high enough to say we must do something about it right this very second. It's intermediate, as the name states, and therefore we have to follow these patients.
Unfortunately, we don't have any good tools other than let's just wait and see what it does.
But it's enough probability

Page 148

that -- or enough of them progress that we can -- that we have to say that we need to follow them more closely than a person who doesn't have anything in their liver.
BY ATTORNEY VAUGHN:
Q. And you agree that Mr. Roberts' LR-3 in 2016 had a 15 to 68 percent chance of decreasing to an LR-1 or LR-2?
A. Based on available image -- literature, yeah.
Q. And so would you agree it's most likely that Mr. Roberts LR-3 in 2016 would have either stayed as an LR-3 or decreased to an LR-1 or 2?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I have -- we're looking at probabilities as they apply to the entire population and it comes to -- so if you said -- if, you know, any given LR-3 has a -- then it's

Page 149

true. The problem is applying population probabilities to a particular patient is difficult, because it is a very specific lesion we're talking about.
Because we cannot say with any degree of reasonable certainty that this particular lesion in Mr. Roberts' case would actually regress or stay the same, that is why this lesion requires a follow-up, because there's no way to say how this lesion will behave, because there is up to 24 percent chance of progression and -- and if it progresses, it's an aggressive disease.
So the goal is to monitor and if they, you know, resolve, then the patient can go back to a routine surveillance schedule.
By the way, patients once they have cirrhosis have to be under routine surveillance, so

Page 150

having cirrhosis and even having nothing, meaning that -- let's say if you have a patient who has cirrhosis and they have an imaging, CT or MR, and there's nothing -- there's not a lesion in this liver, that patient still requires fairly close monitoring because presence of cirrhosis indicates the patient is at risk for HCC and it has to be monitored.

BY ATTORNEY VAUGHN:

Q. You just testified that there's no way to tell if an LR-3 will progress to HCC; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: Other than following it up.

BY ATTORNEY VAUGHN:

Q. And then in your 2023 study, you also noted that some retrospective studies have identified independent

Page 151

predictors of progression, such as hep C virus, personal history of HCC, threshold growth, presence of arterial hyperenhancement, size greater than 10 millimeters, T2 hyperintensity, diffusion restriction, and HBP hypointensity.

Did I read that right?

A. Yes.

Q. And do you agree with what you said here in your publication?

A. Yes, but finish the sentence: But other studies have failed to show associations of these factors with outcomes. That's why I'm saying -- some studies say, you know, this feature is associated with progression. There are also studies that fail to show this. That's why we don't have a good way of determining what will progress, what will not, other than following it up.

Q. How many studies say that those independent predictors do indicate risk of it progressing to HCC?

ATTORNEY ROSE: Object to

Page 152

the form.

THE WITNESS: I'm not -- I'm not sure I followed your question.

BY ATTORNEY VAUGHN:

Q. Are there more studies that say that these independent predictors are valid to use to see if it will progress to HCC or are there more saying that these are irrelevant?

ATTORNEY ROSE: Object to the form.

THE WITNESS: I couldn't tell you off the top of my head how many studies, you know, state one versus another.

The point is that the data that we have right now is insufficient to say only lesions that, say, are over 10 millimeters need to be followed or only lesions that have T2 hyperintensity need to be followed. We just don't have that data; therefore, anybody with LR-3

Page 153

observation needs to have three to six months' follow-up.

BY ATTORNEY VAUGHN:

Q. If a patient had multiple of those independent predictors of progression of HCC, would they be at higher risk in your opinion of an LR-3 turning to HCC?

A. If -- if a -- if the lesion had more than one of these features present, I would not categorize it as LR-3. I would categorize it as LR-4.

Q. Why does your publication then talk about stratifying LR-3 and list these?

ATTORNEY ROSE: Object to the form.

THE WITNESS: Because we have some data, but the data is inconsistent and insufficient to say, if you have -- if you don't have these, don't worry about them. We just don't have that data.

Page 154

So you can see the next sentence: Reliable and accurate stratification of LR-3 and LR-4 observation has been identified as a major unmet clinical need by National Institutes for Health, provided so you can see that -- as I -- I think I -- I believe I mentioned that before, that this is an important -- an important thing that we encounter in clinical practice a lot and, again, the -- there's a really significant need to say -- to have some sort of reliable method to say, this lesion will progress, this lesion will not, and right now we don't have that reliable method.

The only way -- the only thing that we can do is say that this lesion meets criteria for LI-RADS 3. It needs to be followed up every three to six

Page 155

months.

BY ATTORNEY VAUGHN:

Q. And the National Institutes for Health is saying that not stratifying LR-3s is a major unmet clinical need; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: No. It says that we need to have reliable and accurate stratification methods developed.

BY ATTORNEY VAUGHN:

Q. And, currently, LI-RADS does not have reliable and accurate stratification of LR-3s; correct?

A. Correct.

Q. And that is what the National Institutes of Health is saying is a major unmet clinical need; correct?

A. The major unmet clinical need is the necessity to develop such tools to stratify -- to risk stratify LR-3s and LR-4s.

Page 156

Q. Which currently LI-RADS does not do.

A. Which currently is not available in any system across the board.

Q. Looking at page 11 of that same study you published in 2023, and do you agree that an inherent and intractable challenge in any radiological system is the subjectivity in interpretation?

A. Yes.

Q. And that includes even features that are reported numerically, such as size, are subject to interreader variability?

A. Yes.

ATTORNEY VAUGHN: Kathryn, can we do the 2018 article by Dr. Chernyak next?

ATTORNEY AVILA: Okay. This is Exhibit 7.

- - -

(Deposition Exhibit No. Chernyak-7, Review Article by

Page 157

Chernyak, et al, "Liver Imaging Reporting and Data System (LI-RADS) Version 2018: Imaging of Hepatocellular Carcinoma in At-Risk Patients", was marked for identification.)

- - -

BY ATTORNEY VAUGHN:

Q. Are you familiar with this study, Dr. Chernyak?

A. This is a review article. It's not a study.

Q. Oh, I'm sorry. This publication.

A. Yes.

Q. You were the lead author on this publication?

A. Yes.

Q. In 2018?

A. Yes.

Q. And it was published in -- is this Radiology, is that a journal?

A. Yes.

Page 158

Q. Is this peer reviewed?
A. This is the leading journal in our field -- in our field. Yes, it is peer reviewed.
Q. And this study is on LI-RADS; correct?
A. This publication is on LI-RADS, correct.
Q. Sorry. Publication.
We can go to the end of it really quickly on page 13.
A. Page --
Q. Yeah, I'm just looking at the very end of it where it notes author contributions. It says: The guarantors of the integrity of the entire study, VC. Are you VC?
A. Yes.
Q. So you guarantee the integrity of this study?
A. This is a --
ATTORNEY ROSE: Object to the form.
THE WITNESS: This is a

Page 159

standardized templated statement. This is not a study, but I -- does that make sense?
BY ATTORNEY VAUGHN:
Q. So you guarantee the integrity of the publication?
A. As an author, yeah.
Q. And you would be responsible for updating it if anything was inaccurate within it?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Yes.
BY ATTORNEY VAUGHN:
Q. And you had no conflicts of interest at this time, correct, or at least you did not disclose any?
A. I did not have any.
Q. Would you consider at this point you having a conflict of interest, now that you're working for ZHP?
ATTORNEY ROSE: Object to the form.
BY ATTORNEY VAUGHN:

Page 160

Q. If you were to publish this today.
ATTORNEY ROSE: Object to the form.
THE WITNESS: No.
BY ATTORNEY VAUGHN:
Q. If you were to publish this study today, would you disclose that you were an expert in this case?
ATTORNEY ROSE: Object to the form. She said multiple times it's not a study.
ATTORNEY VAUGHN: My apologies.
BY ATTORNEY VAUGHN:
Q. If you published this article today, would you disclose working for ZHP as a conflict of interest?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I -- when we submit the articles, it asks specific things, including consulting, and some -- some

Page 161

journals do ask about expert testimonies, which I would.
I don't remember if Radiology asks for it, so depending on what it asks for. So if it did ask, I would disclose it.
BY ATTORNEY VAUGHN:
Q. Up here at "CT/MRI Technique," it notes: The minimal required and optimal images for CT and MRI are listed in figure 4.
ATTORNEY ROSE: I'm sorry. Brett, what page are we on? I can't see --
ATTORNEY VAUGHN: I'm on page -- it's page 4, 819 of the study, but PDF page 4.
ATTORNEY ROSE: Thank you. I'm there.
BY ATTORNEY VAUGHN:
Q. And do you see what I'm talking about, Doctor, where it says, "CT MRI Technique": The minimal required and

Page 162

optimal images for CT and MRI are listed on figure 4?
A. Yep.
Q. And then I did want to go right down here. In your publication, you note that MRI is more sensitive than CT. You agree with that statement; correct?
A. With the simplest specificity; however, the difference are small and the -- and the comparative performance of CT and MR has not yet been studied in community settings.
I can provide you -- well, one of the papers that I cited in my report actually looked at MRI and CT and we found no statistically significant difference in proportions of HCC between CT/MR with extracellular contrast agent and hepatobiliary agents in the meta-analyses for probabilities of HCC per each category.
This is -- this is 2018. This is the initial study that announced

Page 163

-- initial publication that announced release of version 2018 of LI-RADS and the study that I'm referring to is Lee, et al, study published in 2023.
Q. What does "more sensitive" mean?
A. It means that it is able to pick up disease better or it's more likely to pick up disease when it's present.
Q. This -- right here, it says: Late arterial phase imaging is strongly preferred over early arterial phase imaging to maximize the likelihood of depicting APHE, which is a major feature of HCC.
Do you agree with that statement?
A. Yes.
Q. Can you explain that statement?
A. Arterial -- APHE, A-P-H-E, arterial phase hyperenhancement, is a requirement for noninvasive diagnosis of

Page 164

HCC, and we need arterial phase to determine it, to see it. And it is, late arterial phase has a better chance of showing it.
Q. What is late arterial phase versus early arterial phase?
A. It refers to the timing of acquisition of arterial phase.
Q. Is that the third phase of the CT?
A. It is the first post-contrast phase.
Q. What makes it late versus early?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Certain appearances and feeling of certain vessels in the liver.
BY ATTORNEY VAUGHN:
Q. In the 2016 CT for Mr. Roberts, was it a late arterial phase or early arterial phase?
A. I would have to go back and

Page 165

double-check.
Q. What would you check for that?
A. I would check the appearance of the vessels.
Q. And did you check that at the time you were forming your expert opinions?
A. Yes.
Q. But you didn't note if it was late or early?
ATTORNEY ROSE: Object to the form.
THE WITNESS: It's not a requirement for LI-RADS to -- for -- to note that and even though the late arterial phase is preferred, not having one does not render the exam nondiagnostic or LI-RADS not applicable.
BY ATTORNEY VAUGHN:
Q. And when you say preferred, it's strongly preferred; correct?
A. Strongly preferred because

Page 166

it has a better chance of showing arterial phase hyperenhancement; and as I mentioned, without it, you cannot diagnose something as -- as noninvasive HCC.

I would like to note that in 2016 case, all the lesions were under 10 millimeters, means that there was, by definition, regardless of anything else, they cannot be assigned LI-RADS 5 category.

So if I were reading this case, I would still not -- I -- the recommendation would be the same, follow-up in three to six months, because these lesions are not diagnosable as HCC even if every -- if the timing was perfect and there was an arterial phase hyperenhancement, it still would not allow us to diagnose something as HCC and the patient would just have to come back in three to six months for follow-up.

Q. And you said if all imaging was perfectly done. What if it wasn't

Page 167

perfectly done? You would still just be an LR-3?

ATTORNEY ROSE: Object to the form.

THE WITNESS: This study in 2016 was -- was done in a way that LI-RADS was applicable and there was no need to repeat the study immediately.

There is a category called LR-NC. LR-noncategorizeable is what we assign when a study is so bad that you really can't tell heads or tails. This is not the case.

BY ATTORNEY VAUGHN:

Q. What makes a study so bad that you can't tell --

ATTORNEY ROSE: Object to the form -- object to the form.

THE WITNESS: If the -- if the imaging limitations are such that you cannot determine whether the lesion is more likely to be

Page 168

benign, LR-1 or 2, or more likely to be malignant LR-5 and M.

So in those cases, you apply LR-NC noncategorizeable and you request that the study is either repeated or a different study is performed, but something has to be done immediately.

In the case of such small lesions where HCC diagnosis is not -- cannot be made regardless of anything, you would not demand that the study is repeated immediately. You would recommend the study is repeated three to six months.

BY ATTORNEY VAUGHN:

Q. As this says, APHE is a major feature of HCC. There was no APHE in Mr. Roberts' 2016 scan; correct?

A. Correct.

Q. I want to flip back to your expert report very quickly on page 3. Do you remember earlier we were talking

Page 169

about these seven diagnostic criteria?

A. Categories.

Q. Categories?

A. Uh-hum.

Q. And that's what you put in your expert report, that there were seven?

A. Uh-hum.

Q. And in your 2018 publication, let's go to page 5, you note that there's eight unique diagnostic categories in your publication; correct?

A. So LR-NC is a category, but it's not a diagnostic category. It is noncategorizeable. It has no probabilities because it just -- we can't -- as I mentioned. So it is a category, but it's not considered diagnostic because that means that the lesion is not assessable and it needs to be repeated.

Q. And you didn't include that in your expert report, did you?

A. No, it is not relevant.

Q. So it says: is applied when

Page 170

image omission or degradation precludes categorization.

Can you explain what image omission means?

A. Let's say if all post-contrast phases were not done or the patient -- you know, it was MR, patient is unable to hold their breath, and the arterial portal, venous, and delayed phases are completely degraded and you really cannot tell anything and then all you see is a lesion, let's say on T2-weighted sequences, but you can't really say how this lesion enhances and what it does and so you can't say am I looking at benign hemangioma more likely or am I looking at probable definite HCC or any other malignancy, that is the case where you apply LR-NC.

If you look at publications, LR-NC is actually quite uncommon. Hence, I did not put in my report because it's not relevant to this case.

Q. But there are eight unique

Page 171

diagnostic categories, not seven; correct?

ATTORNEY ROSE: Object to the form.

THE WITNESS: When you look at any publications, they don't talk about LR-NC because, again, it's not a diagnostic category. It's more a communication that this lesion is not categorizeable and the imaging needs to be repeated.

BY ATTORNEY VAUGHN:

Q. And over here, the minimum required images is in figure 4 and this is figure 4 here on page 6, page 821 of the study; correct?

A. Yes.

Q. And for CT, what are the required images?

A. Arterial phase, portal venous phase, and delayed phase.

Q. In the arterial phase, the late arterial phase is strongly

Page 172

preferred, what does that mean?

A. Arterial phase -- late timing of arterial phase has a better chance of showing arterial phase hyperenhancement; therefore, when you calibrate your studies and you set the timing parameters for your CT, it should be done in a way that you should obtain late arterial phase in most patients.

Q. What would happen if it was an early phase instead on the arterial phase? Does that impact anything?

A. You may or may not be able to diagnose -- to detect arterial phase hyperenhancement.

Q. In your opinion, was the arterial phase late in the 2016 scan of Mr. Roberts?

A. I'd have to go back and relook.

Q. And then there's the portal venous phase that this mentions is a required phase.

A. Uh-hum.

Page 173

Q. Can you explain that one again?

A. It's a phase that obtained about 60 to 90 seconds after the arterial -- after the injection of contrast.

Q. And do you have an opinion if the portal venous phase was early in the 2016 CT?

A. There's no such thing as early portal venous phase --

Q. And so --

A. -- or -- not -- there's no -- it's a continuum, so, really, early portal venous phase is late arterial phase.

Does that make sense?

Q. Uh-huh.

A. It's a continuum.

Q. So if the portal venous phase was done early, it would actually be a late arterial phase and there would be no portal venous phase?

A. Yes.

Q. And it mentions the delayed

Page 174

phase of two to five minutes after injection. Can you explain that one to me?
A. It's an acquisition done two to five minutes after contrast is injected.
Q. And is it important that it's done two to five minutes afterward?
A. That's usually the timing of delayed phase that is recommended when you create the protocols for your CT scanner.
Q. And do you consider this the most important phase?
A. No, you cannot say that.
Q. Do you have an opinion on which of the three is the most important phase?
A. You need all three to make LI-RADS --
Q. Okay.
A. -- at least you need -- at the very least -- at the very least, you need arterial -- it's a complicated

Page 175

discussion because you have to take into account the -- you know, the patient -- the patient population you're working with and exposure to radiation therapy.
For example, I work, you know -- in the two of the institutions I've worked on, the delayed phase was routinely omitted because -- because we wanted to reduce amount of radiation we subject our patients to, so we routinely would get arterial and portal venous phase.
In other institution I've worked, routinely they've obtained all four phases, meaning precontrast, arterial, portal venous, and delayed and there they were not as concerned about radiation exposure as the other institutions, institutional preference.
There are studies that show that you actually can omit a portal venous phase and just acquire arterial and delayed phase and -- because if you see the washout in delayed phase, that's

Page 176

sufficient. You can apply washout to either portal venous or delayed phase.
So there are institutional preferences that -- that are in place.
Q. But your publication says that all three phases are required to apply LI-RADS; correct?
A. As of 2018, yes.
Q. And so you're saying that's changed since 2018?
A. Again, there's at least one study that came out that showed you can omit the portal venous phase.
Q. Is that your study?
A. No.
Q. Do you agree with that study?
A. I actually do.
Q. Are you going to update your paper?
A. We are discussing it.
Q. And so is there a split opinion on if it should be required or not?

Page 177

A. As it pertains to the liver imaging, it can be omitted. The question is, when you talk about it -- because we're not just looking at liver, right, we're looking at other organs.
So the question is, we need to know, if you omit the portal venous phase, are you -- are you -- how will this affect other organ appearances? That's the conversation that we're having.
Q. And your specified as currently -- scratch that. I mumbled a bunch.
You're currently having a conversation if all three phases are required in the CT for LI-RADS; correct?
A. It's --
ATTORNEY ROSE: Object to form.
THE WITNESS: It's a conversation that is being had by the technical working group. I cannot tell you what the final

Page 178

decision will be.
ATTORNEY VAUGHN: Nina, what time do you want to do lunch today?
ATTORNEY ROSE: I'm happy to stop now if that works for you or we can keep going --
ATTORNEY VAUGHN: We haven't been on the record a ton, but like I'm at a pretty good time for a break if we want to do lunch. I know that you're on East Coast. Right?
ATTORNEY ROSE: We're both on East Coast.
ATTORNEY VAUGHN: You're both on East Coast? Yeah, do you want to go ahead and do lunch now?
ATTORNEY ROSE: Yeah, that's fine, that works.
THE VIDEO TECHNICIAN: Off record, 12:08.
(A luncheon recess was taken from 12:08 p.m. to 12:53 p.m.)

Page 179

THE VIDEO TECHNICIAN: We are back on the record at 12:53.
BY ATTORNEY VAUGHN:
Q. Doctor, I want to go to page 8 of your expert report, which I believe is Exhibit 2. And, Doctor, do you plan to tell the jury that Mr. Roberts might have had cancer in 2016?
A. Mr. Roberts had lesions which had about 33 percent chance of having cancer in 2016.
Q. And so would your -- sorry. Go ahead.
A. I cannot definitively rule out that he had cancer. I cannot definitively rule in. I can only provide probability based on imaging features.
Q. Would you agree that a 33 percent chance is equivalent to saying he might have cancer at the time in 2016?
ATTORNEY ROSE: Object to the form.
THE WITNESS: If I were to use the certainty lexicon adopted

Page 180

by Memorial, it would be possible.
BY ATTORNEY VAUGHN:
Q. Possible, not probable; correct?
A. Possible, yep.
Q. You note the growth of HCC is variable. What do you mean by that?
A. It means that there are some HCCs that grow very quickly; some HCCs grow relatively slowly.
Q. What type of HCCs grow relatively quickly?
A. I'm not certain what you're asking me.
Q. You testified some types of HCCs grow very quickly. Which types of HCCs grow very quickly?
A. It's not types. It's the -- you know, the -- even though we talk about HCC as a single entity, it's, you know, the -- each individual tumor, just like people, are -- you know, have some individual genetic blueprint, environmental blueprint. So some HCCs

Page 181

grow faster, some HCCs grow slower, again, just like with LR-3.
Unfortunately, our diagnostic tools are relatively crude, so, you know, we talk about HCC as a single entity, but, you know, there are some variabilities within it.
So some grow quickly, some grow slowly and just it -- sometimes -- it's actually not possible to predict by looking at the scan which HCC is going to grow fast or not.
Q. Just by looking at the scan, you can't tell; correct?
A. If it's going to grow fast or not, no, you can't.
Q. But would the underlying etiology for why the HCC developed impact if it is going to be a fast-growing HCC or slow-growing HCC?
A. Not to my knowledge.
Q. Have you researched that?
A. I'm sorry?
Q. Have you done research into

Page 182

that?
A. I have looked into literature when I was giving a recent talk about growth patterns, so -- I have not encountered a single paper that talks about etiology and rate of growth.
Q. And so you've never read any literature that says that HCC caused by hep B is more aggressive?
A. Well, first of all, more aggressive is not always equivalent to faster growth, but no.
Q. Can you explain to me the difference between aggressiveness and faster growth?
A. There are things other than growth that can indicate aggressiveness.
Q. Can you explain those to me?
A. Vascular invasion; if the tumor extends into adjacent blood vessels, that's -- that's a feature of aggressiveness. There are subtypes of HCC which -- which are associated with more aggressive phenotypes, meaning that

Page 183

they are more likely to not respond to treatment or recur after treatment.
Again, unfortunately, these are not something that we can predict based on imaging. We can -- at least not accurately, so...
Q. An HCC that is caused by NASH cirrhosis, would you expect that to be quick growing or slow growing?
A. It depends --
ATTORNEY ROSE: Object to the form. I'm sorry. I'm sorry. I didn't mean to speak over you, Doctor.
THE WITNESS: That's okay. It depends on the lesion and there's no way for me -- again, when I look at the scan, there is no way for me to predict that this particular HCC's going to grow fast or slow.
You know, it -- I have cases where a very small HCC doubled in size in six weeks. I have cases

Page 184

where a large mass over, you know, 31/2 centimeters, grew size wise very minimally in the course of eight months.
It's impossible to predict for any -- for particular lesion. We can talk about population what on average can happen, but, you know, again, apply population statistics to a particular case is always problematic.
BY ATTORNEY VAUGHN:
Q. And you're only reviewing imaging. You're not reviewing Mr. Roberts' case-specific factors, such as his medical history and other risk factors; correct?
A. Correct.
Q. You note two-thirds of HCCs have a tumor volume doubling time of three months or longer; correct?
A. Yes.
Q. And so would you agree that HCCs with a tumor volume doubling time of

Page 185

three months or less are fast growing?
A. Okay.
Q. Do you --
A. I mean, it's not -- fast growing, slow growing is not a medical concept.
I can only provide -- the data is, you know, generally we accept that, in general, we have the feature called threshold growth and we -- and it's 50 percent or greater size increase in -- within six months, that's accepted as threshold growth. But we also know that some HCCs don't meet that criteria. Some do.
While it's true that HCC -- all HCCs grow over time, predicting the rate of growth is very problematic because, you know, any particular HCC, it's not a steady growth, right, it can -- it can kind of not grow for a little bit, then grow, then stop growing.
So the -- so the rate of growth is not constant for any -- for

Page 186

even particular with a lesion that we follow over time, you know, that there's -- there's -- the only definitive thing we can say more or less is that HCCs don't become smaller without treatment.
Q. Would you agree that most HCCs take three months or longer to double in size?
A. The volume, the volume.
Q. It takes three months or longer for most HCCs to double volume; correct?
A. Yes.
Q. Then why in this case did you assume a tumor doubling volume time of three months?
A. Because that's the median.
Q. What do you mean?
A. Median?
Q. Yeah.
A. Means that it's in the center, the value's in the center.
Q. Isn't it only one-third of them are doubling at three months or

Page 187

less?
A. So the -- again, the way that you -- the six months -- the six months of 50 percent size increase is based on three months' tumor volume doubling time, so that's an accepted statement.
Q. But two-thirds of HCCs wouldn't double that quickly; correct?
A. Two-thirds would -- of HCCs would double at least this quickly -- right, this quickly or longer, yes.
Q. And by longer, you mean slower, like four months or five months?
A. Yes.
Q. And then why -- so why is it that you assumed the faster growth rate?
A. It's not fast. It's median. It's median -- it's median -- it's a median value that we assume which is used by -- like, that's the value that's used to arrive at -- at the threshold growth value of six months.
Q. How did you calculate this

Page 188

median?
A. It's just data.
Q. So you're applying the fastest one-third growth and you're saying that's the median?
A. That is the data that is used to arrive at the threshold growth, so that's the data that's used -- that's the assumption that's used by UNOS, by LI-RADS. It's the threshold growth of six months.
Q. What is threshold growth?
A. Size increase, the longest dimension increase of 50 percent or greater.
Q. Do you need two images to determine threshold growth?
A. You need to have a study that is at least -- that is done at least within six months prior --
Q. And do you have that with Mr. Roberts?
A. No.
Q. Then how can you apply

Page 189

threshold growth to Mr. Roberts?
A. I was providing the theoretical numbers. I'm not -- right?
Q. So you don't have the actual imaging necessary for threshold growth on Mr. Roberts, correct, you're just applying theoretical numbers?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I was providing the possible scenario of how would -- how would a 5 millimeter lesion progress to -- could progress to 5.6 centimeter lesion.
BY ATTORNEY VAUGHN:
Q. You were given a possible scenario, not a probable scenario; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I'm not sure how to -- again, I cannot predict how things grow, any particular

Page 190

lesion.
BY ATTORNEY VAUGHN:
Q. So you're having to guess; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I'm providing numbers.
BY ATTORNEY VAUGHN:
Q. And you made this assumption that it would double in size or in volume every three months and you come to the calculation that it would take two years and eight months for that tumor to go from the half centimeter size that you saw in 2016 to the 5.8 centimeter size saw in 2018; correct?
A. Yes, but it says assuming constant growth, and as I mentioned, the growth is usually not constant.
Q. So are you opining that you think the growth in Mr. Roberts might have been even more aggressive than a tumor volume doubling time of every three

Page 191

months?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I cannot -- I was just -- I was asked to provide -- so the statement was, it was -- here's the statement -- I was asked to respond to statements. Right?
The statement was that his cancer is more aggressive, were to progress faster, and I was providing numbers that -- there's -- there's nothing in -- in my opinion in Mr. Roberts' progression or course of development of HCC that's outlandishly impossible without -- or -- you know, without just having H -- you know, cirrhosis. Right?
So as I said, it's very common in my experience that we have a patient who presents with

Page 192

advanced HCC and prior imaging shows nothing.
The numbers that I'm providing you here are not outlandish. This is what would have -- what could -- what should have happened if -- right, if we assume this very reasonable tumor volume doubling time.
So what I'm trying to show that the numbers are not outlandish and they're not -- he's -- assuming that his original lesion progressed to his final lesion, the progression is not outlandishly fast. It's reasonable.
BY ATTORNEY VAUGHN:
Q. And you can't say with a reasonable degree of medical certainty that that initial lesion actually did progress into HCC; correct?
A. I cannot exclude this possibility.

Page 193

Q. And what do you mean by that? You can't for 100 percent certainty that it didn't?
A. Without having --
ATTORNEY ROSE: Object to the form.
THE WITNESS: I'm sorry. Without having interim imaging, which should have happened, I cannot tell you what exactly happened, because he -- you have an imaging and then two years and four months later, you have another imaging.
What should have happened is that in between these two time points, there should have been at least every six months imaging, at which point you could say, okay, this is what happened to this lesion.
Without having, you know, what's in -- you know, without having the required imaging in

Page 194

between, it's not possible to say what happened.
BY ATTORNEY VAUGHN:
Q. And so without that imaging in between, you're having to speculate; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I am providing -- I'm stating that you cannot exclude a possibility that this LR-3 lesion progressed to LR-5. It's possible.
BY ATTORNEY VAUGHN:
Q. But you want to tell the jury there's a chance the LR-3 progressed to LR-5; correct?
A. There's a chance.
Q. And using these assumptions that you used, it would take approximately two years and eight months for it to grow from that .5 to the 5.8; correct?
A. Yes.

Page 195

Q. And how many months were between that CT scan in 2016 and the MRI in 2018?
A. Two years and four months.
Q. So even by your calculation, it wouldn't have been that size when they did the MRI; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Four months, yeah. As -- as I mentioned, this assumes a constant tumor volume doubling time.
Unfortunately, while -- you know, unfortunately, there's dearth of data to provide you with exact growth curve of HCCs because generally once HCC is diagnosed, it's treated, we don't tend to follow them.
So the -- you know, my -- my experience with -- you know, with longitudinal untreated HCC growth is limited, just like it is

Page 196

limited for anybody, because again, we don't follow these patients.
The only data we have is patients who get lost to follow-up, who doesn't get followed, so that we can retrospectively come back and say this is what happens. But we don't intentionally follow these patients.
So -- however, in my experience, in my experience, HCCs don't grow constantly. They grow -- they grow, then they kind of pause, then they grow faster, then they pause, then they grow faster.
It's a very -- not a constant growth pattern, so it is not, you know -- if I gave you here a calculation of two years and eight months, two years and four months is not -- is -- would -- it's essentially statistically

Page 197

the same thing and it's not -- it's not inconsistent with the statement.
BY ATTORNEY VAUGHN:
Q. And so you assumed a constant tumor volume doubling time, but you don't think that Mr. Roberts had a constant tumor volume doubling time; correct?
ATTORNEY ROSE: Object to the form; misstates the witness' testimony.
THE WITNESS: The -- the statement was that his cancer is more aggressive and progresses faster. I'm providing numbers that show that his growth is within the -- what's would be expected for -- you know, for a patient who has cirrhosis and unfortunately left to develop HCC, not undergo surveillance.
We know that surveillance improves survival of patients with

Page 198

cirrhosis by detecting HCC at stages where it can be treated.
So I was just providing numbers. These numbers -- nobody can provide you with exact numbers because, again, there was no follow-up that was required -- that should have happened.
BY ATTORNEY VAUGHN:
Q. So you have no way to know if this assumption that you made of a constant tumor volume doubling time of three months was applicable to Mr. Roberts; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I am showing that it is within the realms of possibility that this was so.
BY ATTORNEY VAUGHN:
Q. In your expert opinion, did Mr. Roberts' HCC have a constant growth rate?
A. This is not an answerable

Page 199

question because I don't -- because the patient didn't have the follow-up, so...
Q. Can you explain to me how you did this calculation, this tumor volume doubling time, to come to your answer that it would take approximately two years and eight months for it to grow to the size that was seen?
A. There is a -- a calculator you can plug in. There's a formula. You can plug in the numbers. So I said, you know, tumor volume doubling time three months, initial size this, and it -- and the calculator spit out the two years and eight months using the formula. I can look up the formula for you.
Q. What calculator did you use?
A. ChatGPT, which provided me with --
Q. ChatGPT?
A. Well, it provided me with a formula, so I can --
Q. So you entered some data in this ChatGPT and it shot out it would

Page 200

take two years and eight months for it to grow to that size?
A. It provided me with a formula which -- which is the formula you use for -- for this. I looked at the formula. It was correct. It just made the calculations faster than me entering into Excel and recalculating everything myself.
Q. And did you include ChatGPT's formula in your expert report anywhere?
A. No.
Q. How would I find what ChatGPT's formula was?
A. It's in -- it -- it's a standard formula for tumor -- tumor volume doubling time. There's a -- there's a formula and it just made the calculation faster.
Q. Does that formula appear anywhere in your expert report?
A. No.
Q. Does the data that you

Page 201

entered in that formula appear anywhere in your expert report?
A. Yes, three months and .05 centimeter.
Q. So is all you typed into ChatGPT was three months and 0.5 centimeters and ChatGPT shot out that it's going to take two years and eight months?
A. I said tumor -- tumor volume doubling time is three months. Initial size is .5 centimeters. How long will it take to grow to this 5.8 centimeter? It provided me with step-by-step calculations. They appeared correctly.
Q. For the tumor volume doubling time of three months, you chose the three-month doubling time, not ChatGPT; correct?
A. Yes.
Q. Did ChatGPT give you a suggestion of what doubling time you should be using?
A. No. It just provided me

Page 202

with calculations to make my report faster. I could have taken the time of putting this formula into Excel and I would have arrived at the same. It was just faster to do this way.

Q. Did you not have time to do that for this expert report?

ATTORNEY ROSE: Object to form.

THE WITNESS: No, as I'm not a mathematician, as I'm not a statistician, it was a -- as I'm a radiologist, so I was focusing my energy on radiology and using the available tools, which are used routinely by many people.

BY ATTORNEY VAUGHN:

Q. Do you use ChatGPT routinely in your practice?

A. Not in my practice, but if I need to calculate something...

Q. So in your practice, you don't calculate tumor volume doubling times with ChatGPT; correct?

Page 203

A. No.

Q. Did ChatGPT ask you if he had hep B infection or any type of viral infection?

ATTORNEY ROSE: Object to the form.

THE WITNESS: ChatGPT didn't ask me anything, because I didn't even -- I literally provided numbers and said put it into formula and spit out the numbers, so it didn't know -- it had no information other than tumor volume doubling time, initial size, and the final size.

BY ATTORNEY VAUGHN:

Q. So ChatGPT also wasn't aware of any of the patient-specific facts to Mr. Roberts, such as his prior medical history or if he had a viral or nonviral etiology, ChatGPT was unaware of that?

ATTORNEY ROSE: Object to the form.

THE WITNESS: ChatGPT only

Page 204

was providing me calculation, nothing else. Just plugged in the numbers to make my life easier.

BY ATTORNEY VAUGHN:

Q. And the only numbers you plugged into ChatGPT was assuming a three-month doubling time and what the initial size of the lesion was?

A. And the final size, yeah.

Q. And how do you type that into ChatGPT? What's the first thing you typed in?

A. Assuming a tumor volume doubling time of three months, an initial size of .5 centimeters, how long will it take to grow to 5.8 centimeters?

Q. And then did ChatGPT show you each stage of the doubling, how much volume and how many centimeters it would be?

A. It showed me the formula that's used and the step by step how we used it and what the answer was.

Q. And do you know what the

Page 205

volume would be at this time at two years and eight months or do you just simply know that that would be 5.8 centimeters?

A. Well, 5.8 centimeters can be transformed into double -- into volume using the formula --

Q. And what volume would that be?

A. Again, so if you have the 5.8 centimeter diameter, so you have to half it to radius, right, so radius -- I think it's PR -- I don't remember this -- like, I don't remember off the top of my head the formula for sphere.

I -- you know, I'm not -- again, I'm not a mathematician, so I doubt people walk around with that knowledge. But I could look it up and say, you know, what's the volume for this sphere?

Q. Would you need to ask ChatGPT for that?

A. I can ask Google.

Q. Google. Okay.

Page 206

HCCs, do they typically grow from the center outwards proportionally?
A. Depending on the type of -- it depends.
Q. Depends on what?
A. Depends on the growth type. There's some -- some that do like that, then they grow from the center outwards. Some have what's called cirrhotomimetic growth pattern where just they -- the lesions look like multiple cirrhotic nodules and they may spread out outwards in the form of nodules. That's less common.
Most common is you have a nidus and over time, you have a cirrhotic nodule and over time, after -- you know, then you have progression to high-grade dysplastic nodule.
And then you have progression into early HCC that replaces -- and eventually there's progression to progressed HCC. That replaces the underlying nodule and then expands

Page 207

outwards. That's a more common pattern.
Q. Are there any factors that help predict what type of growth pattern you will see?
A. No.
Q. Does cancer require blood supply?
A. HCC, yes.
Q. The lesion that you identified in 2016 that you believe might have turned into HCC, did you see any blood supply near that lesion?
A. It was not a dead lesion, therefore there was a blood -- I mean, it was -- I'm not sure how to answer your question.
Q. Were there any major vessels near the LR-3 that you identified that you believe might have turned into HCC in 2018?
A. I'm looking at the images from my report. There were hepatic veins nearby. There was a posterior branch, a right portal vein nearby. There --

Page 208

portal venous branch sitting right posterior to it.
But the lesion is in the liver, therefore there's blood supply.
Q. What was the shape of the LR-3 in 2016 that you believe might have turned into HCC by 2018?
A. Rounded.
Q. Spherical?
A. Rounded.
Q. Can you explain the difference between rounded and spherical to me?
A. Sphere is a 3D shape. I'm looking at 2D representation. So on the maximum size, it is -- it is rounded, so -- on series 401, image 24, it looked like a little round -- close to a round circle.
Q. Are you able to determine if it was spherical?
A. We do not routinely utilize 3D extraction tools in clinical practice to provide with 3D implementation.

Page 209

Generally, as you move up and down, as you scroll up and down through the lesion, you get a sense if it's a very long lesion, this was not, so -- and, again, the working assumption is that we're looking at a spheric lesion and using the diameter as a representation of something that can be easily calculated into volume.
Q. And so you had to make an assumption that the initial LR-3 was spherical; correct?
A. That is assumption that is made routinely for these cases, correct.
Q. And at the time in 2018 when he was diagnosed with HCC, what did his HCC look like at that time?
ATTORNEY ROSE: Object to the form.
THE WITNESS: It met criteria for LI-RADS 5.
BY ATTORNEY VAUGHN:
Q. What about shape? What shape was his HCC at that time?

Page 210

A. He had three. Which one do you -- do you want to talk about?
Q. The one that you believe the LR-3 turned into HCC or that you believe might have turned into HCC.
A. Oval-ish.
Q. Oval-ish? So it's not a sphere; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Again, you know, if I did a 3D reconstruction, it would not be -- like, nothing is a perfect sphere, right, because perfect shapes are -- usually don't happen in nature.
We approximate the shape to being an irregular sphere, meaning it's not perfect, but it's as close to sphere as nature makes it.
BY ATTORNEY VAUGHN:
Q. You didn't do a 3D reconstruction in this case, did you?

Page 211

A. I did not. I interpreted this case like I would interpret it in real life, in my practice, which is where we provide the longest dimension, which is what LI-RADS requests.
Q. You note that his progression would be consistent with the normal observed progression of HCC?
A. It's not outlandishly fast.
Q. What do you mean by outlandishly fast?
A. Look, if you showed me -- if you showed me his 2018 scan and then six months before, there was not a single lesion, I would say this is quite unusually fast.
Q. What about 12 months?
A. I've seen cases.
Q. How many?
A. Many.
Q. What percentage of cases you've seen have grown that quickly within 12 months?
A. Within 12 months? I've

Page 212

seen. I have a collection.
Q. How many patients have you seen over your career?
A. With HCC?
Q. Yeah.
A. A lot.
Q. Can you give me a percentage of how many would progress that quickly in 12 months?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Again, there's no -- I cannot give you this -- we don't follow patients with HCC routinely.
So it's not impossible, but I can't give you the precise percentage, just -- there's no data on this and...
BY ATTORNEY VAUGHN:
Q. It could happen though.
A. It could happen, 12 months, but, again, we have no 12-month study prior here.

Page 213

Q. Go to page 9 of your report real quick. You gave the opinion that Mr. Roberts' cirrhosis was the most likely cause of his HCC; correct?
A. Yes.
Q. But, again, you did nothing to look into Mr. Roberts' medical records other than his imaging; correct?
A. Correct.
Q. You didn't look into his pharmacy records; correct?
A. Correct.
Q. You don't know the total dose of NDMA that he was exposed to; correct?
A. Correct.
Q. And you've done no research on NDMA; correct?
A. Correct.
Q. But you want to go and tell the jury that the most likely cause of his HCC was cirrhosis?
A. Yes.
ATTORNEY ROSE: Object to

Page 214

the form.
BY ATTORNEY VAUGHN:
Q. Without -- without considering any of his other risk factors, you want to go in and tell the jury that the most likely cause was cirrhosis for Mr. Roberts' HCC.
ATTORNEY ROSE: Object to the form.
THE WITNESS: HCC is the sixth most commonly diagnosed cancer in the world and 80 percent of HCCs occur in patients with cirrhosis.
Every guideline, LI-RADS included, once you have the diagnosis of cirrhosis, you're considered to be at high risk for HCC, which means that we can apply imaging criteria to diagnose the HCC noninvasively, which means that the patient is supposed to undergo routine imaging surveillance and this is a

Page 215

cost-effective strategy to prevent advanced HCC from happening.
I'm not aware of a single guideline that says look at patients from a collagen exposure to determine whether this patient is at high risk for HCC.
So just statistically speaking, since 80 percent of all HCCs in the world occur in patients with cirrhosis and cirrhosis is recognized as a major risk factor for HCC so that you can diagnose HCC noninvasively, which I understand you're not -- you're not a physician, so -- so it may not seem very amazing to you, but HCC is the only solid malignancy in abdomen and pelvis where we can be so precise with imaging, that we don't need to -- we don't need to confirm a diagnosis with biopsy. It's actually quite remarkable.

Page 216

But it only works, only works -- and I cannot underscore this enough -- it only works in patients who fall into high risk as defined by LI-RADS population.
So when I teach people, residents, other physicians, about LI-RADS, I -- this is a point that's stressed again and again and again: This only works in patients who have high enough pretest probability of HCC. And it works. We have a lot of data to show that LI-RADS works. Okay?
So if the scan that Mr. Roberts had has cirrhosis, which means that he falls into LI-RADS definition and AASLD definition and UNOS definition and EASL definition and KCL definition, APASL definition of a person who is at high risk for HCC, as a radiologist, I don't need to look at anything else. This is

Page 217

sufficient for me to say the patient is at high risk for HCC. LI-RADS is applicable. I can provide the LI-RADS categories for any lesion that happens and I can -- you know, as in 2018, when he developed LI-RADS 5 lesions, he didn't have to have a biopsy proof.
He -- we know that he had HCC and it was diagnosable precisely because he has underlying risk factor for HCC, so --
BY ATTORNEY VAUGHN:
Q. And that's in 2018. You can't make a diagnosis in 2016 off LI-RADS; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Incorrect. In 2018 -- if in 2016 he had a lesion that met criteria for LI-RADS 5, I would have been able to diagnose

Page 218

--
BY ATTORNEY VAUGHN:
Q. But he did not have a lesion that met LI-RADS 5 in 2016, did he?
A. He did not have a lesion that met the criteria for LI-RADS 5, but LI-RADS was applicable and the lesions that he did have had a category assigned to them, which is LI-RADS 3.
Q. And with LI-RADS 3, you cannot diagnose him with HCC, can you?
A. Not with precision that obviates the need for biopsy.
Q. Not to a reasonable degree of medical certainty, you can't say he had HCC in 2016, can you?
A. He -- his lesions had a 33 percent probability of being HCC at 2016.
ATTORNEY VAUGHN: Do you have the 2018 LI-RADS stuff, Kathryn?
ATTORNEY AVILA: This will be Exhibit 8.
- - -

Page 219

(Deposition Exhibit No. Chernyak-8, CT/MRI LI-RADS v2018 CORE Document, was marked for identification.)
- - -
BY ATTORNEY VAUGHN:
Q. Dr. Chernyak, did you produce this document in response to your notice for deposition?
A. Yes, I think so.
Q. And what is this document?
A. This is a CORE -- did I say -- yep, this is the CORE document that is available to all radiologists explaining how to use LI-RADS, how to apply LI-RADS.
Q. What percent of people with cirrhosis never develop HCC?
A. The probability -- the annual incidence of HCC of patients with cirrhosis is 2 to 4 percent.
Q. So after two years, 92 percent of people with cirrhosis wouldn't have developed HCC; is that correct?
ATTORNEY ROSE: Object to

Page 220

the form; misstates testimony.
THE WITNESS: What was the last --
BY ATTORNEY VAUGHN:
Q. So you said 2 to 4 percent of people with cirrhosis develop HCC per year.
A. Yes.
Q. You were saying that Mr. Roberts had cirrhosis in 2016.
A. Yes.
Q. What was his odds of developing HCC then by 2018?
A. He at 2016 already was not a, quote, unquote, general population of cirrhotics. He had a -- he had three lesions. So -- I can't calculate those odds.
The probability -- we discussed, the probability that any one of those particular lesions would progress to -- diagnostically to HCC in two years and four months is about 20 percent based on the study that we

Page 221

discussed.
Q. And is this LI-RADS 2018, is this like a guidance document? How would you describe this document?
A. This is called a CORE document. It means that -- it means that let's say you want to apply LI-RADS and if you're not familiar, you would open this up and it tells you step by step how to apply LI-RADS.
Q. And for diagnostic categories, it lists 1, 2, 3, 4, 5, 6, 7, 8; correct?
A. Yes.
Q. And you only listed seven in your expert report; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: As I mentioned before, as you can see, LR-NC is -- is put in slightly separate. It's not categorizeable. It's really not a category so much as communication to a physician that

Page 222

the imaging that we obtained is insufficient to make reasonable determination of whether or not the lesion is more likely to be benign, more likely to be malignant. It means that the patient needs another story.
BY ATTORNEY VAUGHN:
Q. Did you evaluate the sufficiency of the imaging done in Mr. Roberts in 2016?
A. Yes.
Q. Here on page 8, it talks about patients not to apply LI-RADS in; correct?
A. Yes.
Q. One of these is those with cirrhosis to congenital hepatic fibrosis. Now, you never reviewed Mr. Roberts' medical records to see if he had any congenital abnormalities or issues with his liver dating back to before he was 18; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I believe that there was -- there was -- well, I had the report, right, of ultrasound and ultrasound stated the patient had steatosis.
Also, patients who have congenital hepatic fibrosis don't necessarily -- well, first of all, they would -- they would not be asymptomatic into the age that Mr. Roberts was --
BY ATTORNEY VAUGHN:
Q. Do you agree that Mr. Roberts was asymptomatic?
ATTORNEY ROSE: Object to the form.
BY ATTORNEY VAUGHN:
Q. In 2016?
A. Based on Dr. Siddiqui's report.
Q. Are you relying on Dr. Siddiqui?
A. Dr. Siddiqui said he was

Page 224

asymptomatic.
Q. Are you relying on Dr. Siddiqui?
ATTORNEY ROSE: Object to the form.
THE WITNESS: That's what she said.
BY ATTORNEY VAUGHN:
Q. Are you relying on her to give your opinion?
A. I'm relying on that statement that there was no symptoms, which is actually quite common.
Q. If he was having liver problems before he was 18, would LI-RADS be appropriate to apply?
ATTORNEY ROSE: Object to the form.
THE WITNESS: But he wasn't.
BY ATTORNEY VAUGHN:
Q. My question is, if he was, would it have been appropriate to apply LI-RADS?
A. LI-RADS is not applicable to

Page 225

pediatric patients less than 18 years old.
Q. What about once -- if he had liver issues when he was -- before 18, even though he is now past 18, is it appropriate to apply LI-RADS?
A. It depends what kind of liver issues he had.
Q. And did you do any investigation into that?
A. I have reviewed the reports and none of them talked about having congenital hepatic fibrosis. I was seeing his heart. His heart didn't look like a patient who had congenital hepatic fibrosis. There was nothing on the imaging to alert me that this patient has a significant cardiac morbidity.
Q. And you didn't review defense expert report Dr. Mohmed, did you?
A. No.
Q. So you don't know if Dr. Mohmed is saying that he had issues going

Page 226

back to before he was 18, do you?
ATTORNEY ROSE: Object to the form.
THE WITNESS: No.
ATTORNEY VAUGHN: Okay.
THE WITNESS: I was -- I was tasked with reviewing imaging and addressing certain statements, which is what I did.
BY ATTORNEY VAUGHN:
Q. But you need to make sure that applying LI-RADS is proper, right, to a specific patient?
A. Based on the imaging I had and the reports that I had for the original imaging, it was proper.
There was no signs of Budd-Chiari syndrome. There was no signs of vascular-related cirrhosis. It has a certain appearance and that's not -- it wasn't --
Q. So you weren't aware of any type of liver problems prior to him being 18; correct?

Page 227

ATTORNEY ROSE: Object to the form.
THE WITNESS: It's not about him having liver problems before 18. It's congenital hepatic fibrosis is a very specific disease. It's not, you know, you have a -- it's like a -- it's a disease.
BY ATTORNEY VAUGHN:
Q. What about all these other things? It lists cirrhosis due to a whole bunch of other things. Did you rule all of that out as well?
A. Yes, based on the imaging, none of these applied.
Q. You can tell all of that through imaging.
A. Correct.
ATTORNEY ROSE: Object to the form.
THE WITNESS: Yes.
BY ATTORNEY VAUGHN:
Q. And we went through these, I

Page 228

believe, earlier. These ancillary features favoring malignancy, you did not see any of these in Mr. Roberts' 2016 scan; correct?
A. Correct.
Q. And then ancillary features favoring it being benign, the size stability of greater than two years, you couldn't see that because you didn't look at the prior imaging; correct?
ATTORNEY ROSE: Objection to form.
THE WITNESS: I didn't have prior imaging available.
BY ATTORNEY VAUGHN:
Q. So you were not able to see the imaging prior to 2016 to see if it was stable in size; correct?
A. Correct. Also, by default, if prior imaging is not available, then -- and size stability and size increase are not applicable if it's --
Q. But prior imaging was available to his treating physicians.

Page 229

Right?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I don't know.
BY ATTORNEY VAUGHN:
Q. You don't know.
A. (Witness shakes head.)
Q. Do you not remember at the beginning of the deposition where we went over where they were comparing the imaging to prior imaging?
A. They were comparing to ultrasound. That's not -- these features that you're pointing out to are not applicable to ultrasound. They're applicable to CT and MR.
Q. Do you know if a prior CT or MR was done on this patient before 2016?
A. I was not given the images from anything before.
Q. Did you notice any of these other ancillary features that would favor it being benign?
A. No.

Page 230

Q. And page 12 talks about tiebreaker rules. Can you explain what a tiebreaker rule is on the LI-RADS?
A. Tiebreaker rules means that if there's any uncertainty between the two categories, the rule is to default to something that provides lowest certainty.
So if I was reviewing the study and I wasn't sure if I should apply LR-3 or LR-2, I would apply LR-3 because it provides a lower certainty of benignity.
If I was reviewing the study and I wasn't sure if I should apply LR-4 or LR-3, I would default to LR-3 because that provides lower certainty of malignancy.
If I was not sure between LI-RADS 5, which is definite HCC, versus LR-M, which is malignant, but not HCC specific, I would default to LR-M, which is lower certainty of hepato-cell origin. It means that it's lower certainty that it -- the tumor arose from primary liver

Page 231

sites. Okay?
So all of these rules are there to preserve the specificity of LI-RADS 5 diagnosis. As I mentioned before, our goal is to make the criteria for LI-RADS 5 so good that you don't need a biopsy once you arrive at LR-5. That means that if there's any uncertainty, you default away from LR-5.
So any uncertainty defaults toward a lower -- toward the category that provides lower certainty.
Q. And so LR-3 provides the lowest certainty out of all the LRs; correct?
A. It provides -- no. It -- LR-3 provides lowest certainty of malignancy and lowest certain of benignity.
Q. And so if you weren't sure between LR-2 and LR-3 with Mr. Roberts, you would call it an LR-3; correct?
A. Yes.
ATTORNEY ROSE: Object to the form.

Page 232

THE WITNESS: Yes.
BY ATTORNEY VAUGHN:
Q. And then it says: Final check. Ask yourself if the assigned category seems reasonable and appropriate.
Can you explain what that means?
A. This means that if you are assigning a LR-2 category -- let's say you are applying an LR-M category and the lesion had been stable for 20 years, you have to ask yourself is it -- is it likely that a malignancy would be stable for 20 years? That's literally what it comes down to, to make sure that what you are saying makes sense.
Q. So you get the LI-RADS and then you see if it makes sense and if it's reasonable for that specific patient; correct?
ATTORNEY ROSE: Object to the form.

Page 233

ATTORNEY VAUGHN: I'm sorry. I couldn't hear your answer.
THE WITNESS: This step is there for that precise reason. You don't assign a category that is -- completely makes no sense.
BY ATTORNEY VAUGHN:
Q. But you have to consider the patient specifically, the patient-specific factors.
A. No. You consider the lesion-specific factors. So, again, if your, you know, lesion was 5 centimeters a year ago and now it's 1 centimeter and you're applying LR-M category, it's probably not -- it doesn't make sense, because again, tumors don't decrease in size without treatment.
That's what this step is there for, to make sure that you're not applying a category that doesn't fit what the imaging is doing. That you're not applying, you know -- that's literally -- that's what it means.

Page 234

It's actually a problematic step that will be removed, because sometimes people use it as, you know, a free for all -- carte blanche to whatever they feel like applying, but that's not -- that's not the intent.

The intent is that you look at it and you make sure that what you're applying makes sense, that you're not applying a definitely malignant category to a lesion that's half in size.

Q. And so do some practitioners take the LI-RADS system and apply it to a specific patient and that's why you're saying this step's going to get removed?

ATTORNEY ROSE: Object to the form.

THE WITNESS: This step was -- was placed in there as a kind of, like, make sure things makes change.

What came to our attention is that occasionally people applied the step incorrectly,

Page 235

meaning, for example, I have a very good colleague who's an expert in HCC and when he applied LI-RADS criteria, they came back -- you know, he should have applied LR-M category, but in his experience, the feature that was present in that particular case made him feel like this is more likely to be HCC than a non-HCC.

So he said, well, I used this final check to revert back to LR-5, but that is problematic because you're not supposed to do that.

So that is why we're probably going to remove the step to make sure that people aren't confused.

BY ATTORNEY VAUGHN:

Q. But it hasn't been removed yet?

A. Yeah, we're working on the -- on the updates. Hopefully, this year,

Page 236

they'll come out.

Q. Do you consider this a current problem with the LI-RADS system?

A. No.

Q. No.

A. So in -- in -- how many -- six years, seven years since -- since its release -- this step has been there for longer, probably for about 10, 12 years. This is the first time that I'm aware that somebody used this step as a carte blanche to go from LR-M to LR-5.

But since it is possible, we probably are going to remove the step.

Q. On PDF page 37, page 35 of the document on the bottom, do you see here where it says: LR-3. Many LR-3s are vascular pseudolesions?

What's a pseudolesion?

A. A lesion that looks like a lesion, but it's not a real lesion. It doesn't have a pathologic correlate.

Q. Do you agree with this statement that's in the guidance

Page 237

documents for LI-RADS?

A. Yes.

Q. And can you put a percentage on how many LR-3s are actually pseudolesions?

A. That's not -- that's not -- that's -- the literature doesn't give me the percentages. The only percentages that we know are percentages of HCC. That's what's studied.

In my clinical practice, it really depends. It depends on the type of study that's done, depending on contrast that's used. I know that inexperienced people assign LR-3 category to things that I would assign LR-2 category.

Mr. Roberts' imaging -- images -- sorry -- lesions did not fall into vascular lesion appearance.

Q. Would some practitioners categorize Mr. Roberts' 2016 lesion as an LR-2?

ATTORNEY ROSE: Object to

Page 238

the form.
THE WITNESS: If they do, it's incorrect.
BY ATTORNEY VAUGHN:
Q. What makes it incorrect?
A. LR-2 means it's -- you are very -- that in your professional opinion, this lesion is most likely benign, but you don't have enough certainty to say hundred percent it's benign.
So there's nothing in this -- in this -- on this scan to indicate that it is -- it's an indeterminate.
I know that the original interpreting radiologist didn't -- excuse me -- didn't provide the LI-RADS category, but they did say it's indeterminate. They didn't know what it was, which is -- which is appropriate.
Q. Could it have been possible that the radiologist at the time didn't think that the imaging qualified for LI-RADS?

Page 239

ATTORNEY ROSE: Object to the form.
THE WITNESS: I have no basis to judge what the original interpreting radiologist thought.
BY ATTORNEY VAUGHN:
Q. A pseudolesion, that's noncancerous; correct?
A. A pseudolesion is a thing that looks like a lesion on the imaging, but has no pathologic correlate.
Q. I'm going to go to PDF page 53 of this document, it is 51 on the bottom. And do you see here, it says: As two recent studies -- as shown by two recent studies, most CT or MRI detected LR-3 observations are benign perfusion alterations or indolent lesions that can be followed safely.
What is an indolent lesion?
A. Indolent.
Q. Indolent? What is that?
A. Indolent means they're not aggressive and can be followed safely,

Page 240

meaning that you don't have to immediately aggressively treat them, biopsy, remove them, but you can carefully watch them and see how they progress.
Q. And it says most of them are -- most LR-3 observations are benign. What does that mean?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Counselor, this -- this is a -- this is a CORE that was released in 2018, as you can see, it is cited. We have many more studies that came out after this.
So at the time, this statement, right, two recent studies showed that the -- in these two studies, the LR-3s that they saw were benign perfusion alteration.
We know, based on follow-up data, including meta-analyses

Page 241

performed on thousands of patients, that 33 percent of LR-3 observations are HCC.
Moreover, the appearance of the LR-3 lesions on 2016 study would not qualify as a benign perfusion alteration because that's not what they look like.
BY ATTORNEY VAUGHN:
Q. This 2018 CORE is still the most current; correct?
A. It is still most current, correct.
Q. It hasn't been -- it has not been revised?
A. We're working on it.
Q. When you reviewed the 2016 CT, was there any enhancement of the lesion that you believe might have turned into HCC?
A. There was no arterial phase hyperenhancement and there was washout. Combination of features -- in combination -- in conjunction with size of -- if you

Page 242

move to page 1 of this CORE document, I will show you how I arrive at LR-3 diagnosis.

So if you see that -- you see on top, you have to go step by step, consider each one of these categories; and then if its LR-NC -- that wasn't the case, right, because there was -- there was nothing that was so egregious that I couldn't say if it's a benign or malignant, so LR-NC is not applicable.

There was no evidence of tumor in vein, so LR-TIV is not applicable. This lesion is not definitively benign, it wasn't a cyst, it wasn't a hemangioma, so not LR-1.

There was nothing in this lesion that made me think that it was probable -- good chance it was benign, so it's not LR-2.

The next step is, does it have targetoid appearance, it did not, so LR-M is not applicable.

So then the next step is to

Page 243

go to diagnostic table. You can see on the bottom, the lesion that is less than 20 -- you know, first thing is, do we have arterial phase hyperenhancement, no. Right? So we are going to stay in the column that says no APHE.

Observation size is less than 20 millimeter. We're going to stay in the most left-hand side of the table. Then we're going to count additional imaging features. Enhancing capsule was not present. Washout was present. Threshold growth was not present because we have no present studies.

So we have one additional major feature. And if you see it on top, right, you see 1, so intersection of 1 and less than 20 is LR-3. So that's what makes me say LR-3.

Because I didn't see any ancillary features of malignancy, I did not alter the category and LR-3 is the appropriate category here.

Q. And so you are saying he

Page 244

only had one major feature and that was washout?

A. Yes.

Q. And my question to you was, did that lesion enhance? When you're saying washed out, did it enhance in that 2016?

A. I did not see arterial phase hyperenhancement on 2016 study.

Q. Did you see enhancement? Is there a difference between arterial phase hyperenhancement and enhancement? Or are those two synonymous?

A. No, they're not synonymous.

Q. Did you see enhancement?

A. That's not part of LI-RADS assessment. I need to see either it's -- either see arterial phase hyperenhancement or not. I did not.

Q. You did not.

A. There's no arterial phase hyperenhancement, which has a very specific definition.

Q. To be clear, you saw no

Page 245

enhancement of the lesion that you believe might have turned into HCC; correct?

ATTORNEY ROSE: Object to the form; misstates the witness testimony.

THE WITNESS: There was no arterial phase hyperenhancement.

BY ATTORNEY VAUGHN:

Q. You just told me that there's a difference between arterial phase hyperenhancement and just regular enhancement. I'm asking you about regular enhancement.

A. I'm not sure how to answer that question because regular enhancement is not defined by LI-RADS. Arterial phase hyperenhancement is defined by LI-RADS and therefore I can apply definition as provided by LI-RADS and say it's not present.

Q. I'm going to go to page 57 of the PDF, it's page 55 down here of the LI-RADS CORE, and the question that was

Page 246

posed in the LI-RADS CORE is: Does washout appearance apply only to observations with APHE? Can you read the answer?

A. No. You can -- counsel, we've discussed this. I said that as long as it's in -- it's iso-enhancing on arterial phase, washout is applicable.

Q. Can you read what the answer is in the CORE for does washout appearance apply only if observations with APHE? What's the answer in that CORE document?

A. No, washout may apply even in the absence of APHE as long as there is some enhancement.

Q. And I just asked you, like, five times was there was some enhancement and you told me no; correct?

A. That's not what I said --

ATTORNEY ROSE: Object to the form.

THE WITNESS: That's not what I said. So, again, I'm going

Page 247

to point something out. This -- this CORE document was released in 2018.

Since then, there are additional documents that were released, including precise definitions of all imaging features, which are available on the same website. I can certainly point it to you.

And because this is a very commonly asked question, the definition of washout was clarified to be very precise, meaning that the lesion can go either from being hyper to liver to hypo to liver or being iso to hypo, so this wording that you're pointing out is outdated.

Yes, this is on the website. Unfortunately, because of how things are, we are not able to update CORE in real life -- in realtime. Excuse me.

Page 248

However, the definitions, the definitions and lexicon, are all available on the same website and it's clearly stated that this is what we we're supposed to refer to. However, what I said is not inconsistent.

Again, as long -- what we cannot do is say something that was, you know, nonenhancing, nonenhancing, nonenhancing and you say it's washout. That's what -- that's what it's getting at.

There is very long -- not very long -- but very complex history, because if you look at the studies which were done before LI-RADS was implemented, there was inconsistencies in how washout was defined.

Some studies would say it has to be applied only to lesions that had arterial phase hyperenhancement. Some studies

Page 249

said, as long as you see something that's looking like hypoenhancing or portal veinous phase, that's what they considered washout.

There's a huge variability in how this feature was defined before LI-RADS defined the features before LI-RADS provided very specific definition of how features were defined, thereby providing a more consistent -- consistent way of assessing things.

So this -- again, there's a follow-up to this document which clarifies how to apply arterial phase hyperenhancement.

The lesions that I saw were isodense on arterial phase and became hypodense on the subsequent phase, which based on the LI-RADS lexicon, which is -- which is available and was updated, that meets criteria for me to say that

Page 250

there was washout.
BY ATTORNEY VAUGHN:
Q. Did you cite this updated criteria anywhere in your expert report?
A. No.
Q. And you produced this document, this 2018 CORE, in response to your Notice of Deposition. Did you produce these updated guidelines that you're now talking about?
A. It's -- I can provide you with lexicon. I was providing this mostly for the first page so you can see how the imaging features are applied and how the diagnostic categories are arrived at.
Q. I want to go to page 15 of this LI-RADS CORE. And we discussed this earlier. These are required images for a CT; correct?
A. Uh-hum.
Q. And these are the same that you listed in your paper that are required; correct?

Page 251

A. Yes.
Q. And then there's a suggested image which is the precontrast phase. You don't have to do a precontrast phase to do a LI-RADS; correct?
A. Not unless the patient had prior treatment. Then it becomes required.
Q. But these other three are all required. Right?
A. Yes.
Q. Mr. Roberts, in his 2016 CT, did they do a precontrast phase?
A. Yes.
Q. Was that phase one?
A. Are you asking me specifically about this?
Q. That's correct.
A. So unfortunately I tried to open this study up, but I think my computer cannot handle the Zoom and stuff, so I actually cannot open the study for some reason.
I'm not seeing the images.

Page 252

Q. Were you able to open that study on your computer previously?
A. Yes, obviously, because I read it.
Q. I didn't know if maybe you were on a different computer.
A. I think that the -- everything else that's running is preventing me from opening it up right now.
ATTORNEY ROSE: Sorry, Dr. Chernyak. Are you referring to one of the exhibits?
THE WITNESS: No. I actually tried to open the actual CT.
ATTORNEY ROSE: Oh, okay.
ATTORNEY VAUGHN: Would it help you if we took a break so you could open up the CT and review everything before we started asking questions on it?
ATTORNEY ROSE: Sorry. I have a question: Are you going to

Page 253

ask her questions about a specific CT? Are you going to introduce a CT as an exhibit?
ATTORNEY VAUGHN: Well, I mean, she's able to go through the different phases, so I thought it might be easier for her to actually look at it herself, but --
ATTORNEY ROSE: Why don't we go off the record and discuss that.
ATTORNEY VAUGHN: Okay.
THE VIDEO TECHNICIAN: Off the record, 2 o'clock.
- - -
(A discussion off the record occurred.)
- - -
(A recess was taken from 2:05 p.m. to 2:20 p.m.)
THE VIDEO TECHNICIAN: We are back on the record at 2:20 p.m.

Page 254

ATTORNEY VAUGHN: Give me one second to get back where I was.
(Pause.)
BY ATTORNEY VAUGHN:
Q. All right, Doctor. And so on the suggested images, it lists precontrast; correct?
A. Yes, sir.
Q. And how do you tell in a CT image if it is a precontrast or if it is a contrast image?
A. You see brightness in the vessels or lack thereof.
Q. Is there any indication as far as like words or letters that would be on the CT to indicate that it was without contrast?
A. I mean, depends on how the scanner is set up. It could say without or pre or WO. Occasionally -- well, we don't have to get into --
Q. Understood.
A. If everything is done

Page 255

correctly, it should be labeled either precontrast or pre or without or C minus or noncon or noncontrast. So there are -- there are multiple ways depending on the facility how it's quoted.
ATTORNEY VAUGHN: And, Kathryn, can you drop in those 2016 CT images of Mr. Roberts now?
ATTORNEY AVILA: Yes, this is Exhibit 9.
- - -
(Deposition Exhibit No. Chernyak-9, 2016 CT Images of the Abdomen, was marked for identification.)
- - -
ATTORNEY VAUGHN: Thank you, Kathryn.
BY ATTORNEY VAUGHN:
Q. And can you see those on my share screen now --
A. Yes.
Q. -- the image?
And so this is series 201,

Page 256

it says down here in the bottom left-hand corner; correct?
A. Yes.
Q. And this 1253, is that what time it was taken, in the top left?
A. It depends. It depends on the scanner setting. Sometimes these numbers are not reliable, so theoretically, it should -- it should provide with the timestamp of the image acquisition. I know that for some of our scanners, it doesn't propagate them. It just shows you when the scan was started, so it's not a reliable measure -- or may not be a reliable measure depending on the scanner is configured.
Q. But is it intended to take the time of when the image was taken?
A. Correct.
Q. And this WO right here, is this indicating without contrast?
A. Yes.
Q. And so the first series was without contrast; correct?

Page 257

A. Yes.
Q. And that is an optional image for LI-RADS; correct?
A. For patients --
ATTORNEY ROSE: Object to the form --
THE WITNESS: -- who do not have --
ATTORNEY ROSE: Sorry. I apologize, Doctor. Just give me one second to --
THE WITNESS: Understood. I apologize.
ATTORNEY ROSE: You can answer.
THE WITNESS: For patients who had prior treatment, it is a required phase. For patients who had no prior treatment, it is often omitted to decrease exposure to radiation.
BY ATTORNEY VAUGHN:
Q. So for Mr. Roberts, this would not have been required for his

Page 258

LI-RADS; correct?
A. Correct.
Q. And then this is the second phase of the image, correct, series 301?
A. This is the arterial phase.
Q. And the arterial phase was taken at 1259 and 20 seconds; correct?
A. Based on the timestamp.
Q. Do you have any reason to disagree with that timestamp?
A. As I mentioned, that depending on scanner configuration, that may or may not be an accurate timestamp. I don't know --
Q. Sorry.
A. I don't know how their scanners are configured, so I -- I -- I believe -- I relied on the date. The timing, you have to be cautious with.
Q. You have no reason to believe that this timing is inaccurate, do you?
ATTORNEY ROSE: Object to the form.

Page 259

BY ATTORNEY VAUGHN:
Q. Are you again just saying it might be inaccurate?
A. I -- I don't consider these numbers. I'm looking at the images, so I see without looking at the numbers that this is the arterial phase.
Q. Did you not look at the numbers of when the scans were done at all when forming your opinions?
ATTORNEY ROSE: Object to the form.
THE WITNESS: It's not a routine practice to look at the numbers.
BY ATTORNEY VAUGHN:
Q. How much after the venous phase -- how long after the venous phase should the delayed phase be?
A. Two to five minutes.
Q. And so right now, we're at 12:59 and 20 seconds. Right?
A. Okay.
Q. And then this is the next

Page 260

series in the CT, correct, which would be series 401?
A. Okay.
Q. And it was done at 1300 and 15 seconds; correct?
(Pause.)
THE WITNESS: Okay.
BY ATTORNEY VAUGHN:
Q. So this image was done 55 seconds after the image before it; correct?
A. Okay.
Q. And this would be the portal venous phase; correct?
A. Yes.
Q. In your opinion, was this portal venous phase done early or on time?
A. On looking at the images, it's done appropriately.
Q. And was there any phase after this?
A. Is this 401?
Q. Uh-huh.

Page 261

A. No.
Q. So there was no delayed phase in this CT, was there?
A. There was no delayed phase on the CT.
Q. And the LI-RADS 2018 CORE says that is a required phase, the delayed phase, doesn't it?
A. It does.
ATTORNEY VAUGHN: I pass the witness.
ATTORNEY ROSE: We can go off the record.
THE VIDEO TECHNICIAN: Off the record at 2:26.
(A recess was taken from 2:26 p.m. to 2:57 p.m.)
THE VIDEO TECHNICIAN: We are back on the record at 2:57 p.m.
- - -
EXAMINATION
- - -
BY ATTORNEY ROSE:

Page 262

Q. Hi, Dr. Chernyak. How are you?
A. Okay.
Q. Dr. Chernyak, are you the co-chair of the LI-RADS steering committee currently?
A. Yes.
Q. Were you able to apply LI-RADS to evaluate the lesions on Mr. Roberts' 2016 CT without having delayed phase images?
A. Yes.
ATTORNEY VAUGHN: Object to form.
BY ATTORNEY ROSE:
Q. How?
A. Yes.
Q. Okay.
A. How? I'm sorry. I thought -- because I saw the washout on the portal venous phase, so once you see a feature on the portal venous phase, that's sufficient for me to say that it's present.

Page 263

There's no requirement that it has to be present on both portal venous and delayed phase. As long as I can see it, I can call it and apply LI-RADS.
Q. Why is the delayed phase important in using LI-RADS?
A. In a minority of HCCs, especially early HCCs, they may not show washout until the delayed phase. So if you don't see the washout on a portal venous phase, you may be missing washout and therefore, you know, delayed phase is supposed to catch that.
However, if you already see the washout in portal venous phase, that's enough to say that it is -- washout is present.
Q. Doctor, do you recall Mr. Vaughn asking you earlier about how you use the tumor volume doubling time to calculate how long it would take for the LI-RADS 3 lesion on Mr. Roberts' 2016 CT to grow?

Page 264

A. Yes.
Q. And you testified that you used ChatGPT as a calculator; correct?
A. Yes.
Q. Were you aware of the formula for using the tumor volume doubling time to calculate the growth of a tumor prior to writing your report?
A. Yes.
Q. And does applying the formula require the use of a scientific calculator?
A. Yes.
Q. Is it fair to say that you used the computing power of ChatGPT to run the math of the calculation you did in the same way that you would use a scientific calculator?
A. Yes.
Q. And would you say that you used the computing power of ChatGPT to run the math of the calculation in the same way you would have used Excel?
A. Yes.

Page 265

Q. Did you use ChatGPT to identify any of the sources you cite in your report?
A. No.
Q. Did you use ChatGPT to generate any sources or articles to support your opinions?
A. No.
Q. Did you use ChatGPT to write any of the text in your report?
A. No.
Q. Did you use ChatGPT to summarize or to understand any of the concepts or literature cited in your report?
A. No.
Q. And did you use ChatGPT for any purpose other than as a scientific calculator?
A. No.
ATTORNEY ROSE: That's all I have. Thank you.
ATTORNEY VAUGHN: All right, Doctor, I'll be really quick.

Page 266

- - -
EXAMINATION
- - -
BY ATTORNEY VAUGHN:
Q. With Excel, you have to put the formula in yourself; correct?
A. Yes.
Q. With ChatGPT, you didn't have to put the formula in; it decided the formula; correct?
A. It showed me the formula as it -- it showed me every step of the calculation so that it was transparent in how every step was applied and how it arrived, basically, at every step of the calculation.
Q. And how do I see every step of the calculation that ChatGPT decided to do?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Do I show you -- should I show you the screen? It literally --

Page 267

BY ATTORNEY VAUGHN:
Q. I mean, is there anywhere in your expert report that I can see the actual formula that ChatGPT applied?
A. No. I didn't put that.
Q. And then I want to go quickly back to the 2018 CORE for LI-RADS.
A. Okay.
Q. Going back to page 57 PDF, where -- at what time did you see enhancement? What phase did you see enhancement, if you saw any enhancement?
ATTORNEY ROSE: Object to the form.
THE WITNESS: On arterial phase, the lesion was iso-enhancing or isodense to the background liver.
BY ATTORNEY VAUGHN:
Q. And isodense to the background liver, does that mean it looked the same as the background liver?
A. Yes.

Page 268

Q. And you think that's adequate enhancement to then say that there was washout in the next phase?
A. As I stated before, in the updated lexicon, there are two patterns that satisfy the diagnosis or characterization of washout. Isoenhancement, isodensity, isointensity, those are all synonyms depending on what modality you used.
So iso, meaning looking the same, and then on the subsequent phase, looking less enhanced, less dense, less intense in hypo or hyper, meaning enhancing more, looking brighter, and then going back to hypo.
Those two are acceptable, equally applicable definitions. I'll be happy to share the reference document with you after we're done.
Q. And, again, this 2000 LI-RADS CORE is what is current today; correct?
ATTORNEY ROSE: Object to

Page 269

the form. I'm sorry. I just want to make sure. Did you say 2000?
ATTORNEY VAUGHN: 2018 LI-RADS CORE, the one we're looking at, this current exhibit, that is current today; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: As I stated before, there are updates that are available on the -- on the website, including, most importantly, the lexicon is clarified and made -- made less -- like, made -- made much more clearer how to apply it.
There's no -- there's no contradiction in the lexicon to what is in the CORE. It's just clarification and more operational definitions so that people are -- it's more clear how to apply these definitions.
BY ATTORNEY VAUGHN:

Page 270

Q. And the 2018 LI-RADS CORE lists a required image as the delayed phase; correct?
A. It -- yes.
Q. And you did not have a delayed phase with Mr. Roberts; correct?
A. Correct.
Q. And when did you realize that you did not have a delayed phase in the 2016 of Mr. Roberts?
A. When I was reviewing the study, as I would review the study in realtime, things don't always function the way you want them to be. For that particular study, what I had was sufficient to apply LI-RADS 3 category.
I knew that the addition of delayed phase wouldn't change that and so I didn't make a big deal out of it because I knew that it would just add to confusion rather than clarity.
Q. So you didn't talk about the fact that there's a missing image that was required because it would cause

Page 271

confusion?
ATTORNEY ROSE: Object to the form.
THE WITNESS: Again, as I think -- I believe I mentioned, there are multiple institutions that choose to omit the delayed phase for the sake of saving radiation exposure to patients.
I've worked at two such institutions -- I'm actually working currently at such institution -- and I apply LI-RADS on a virtually daily basis.
So it is -- is it perfect in compliance with what the CORE says? No. Is it done in clinical practice? Yes. Is it done in clinical practice a lot? Yes.
BY ATTORNEY VAUGHN:
Q. And would you tell your students that the 2016 CT of Mr. Roberts is an ideal scan to apply LI-RADS to?
ATTORNEY ROSE: Object to

Page 272

the form. This is asked and answered.
THE WITNESS: I'm sorry. What was the last thing you said?
BY ATTORNEY VAUGHN:
Q. Would you tell your students that the 2016 CT --
A. No, no -- I'm sorry.
Q. -- of Mr. Roberts is an ideal scan to apply LI-RADS to?
A. Again, great question. And we are working right now on what's called an adequacy score that reflects the adequacy of examination, recognizing that imperfect exam in terms of quality may still be adequate to -- to answer the question.
So right now, a similar score is available for ultrasound, but not for CT and MR, and we are going to introduce a similar score for CT and MR.
So if I were to discuss this case with a student, I would explain to them that in this case, even though this

Page 273

study is not -- would not qualify as a perfect study, it is adequate for answerable clinical question.
So in this case, I would assign as a category B, which means that the exam is not perfect, but adequate to answer a clinical question.
So in this case, the obtained images are sufficient and adequate for me to assign LR-3 category.
BY ATTORNEY VAUGHN:
Q. You said there is a similar score available for ultrasound. What do you mean by that?
A. There -- excuse me. Let me just shift the dog. I apologize.
(Pause.)
THE WITNESS: There is a -- remember I said that there are other algorithms? So right now, there is a -- there's an ultrasound LI-RADS and it incorporates the visualization score as an A, B, and C, which

Page 274

reflects how well an examination is able to assess the liver.
This is not in my report because I was not discussing the ultrasound, but I'm saying that we're using that to model a similar idea for -- for a CT and MR.
So, again, if I were to discuss this case with my student currently, today, that's what I would explain to them, that even though the study is not -- technically meets perfect the requirement, it's still adequate to answer clinical question.
BY ATTORNEY VAUGHN:
Q. And he had an ultrasound done on this 4/8/2016 that you called a CT. Did you attempt to apply the ultrasound LI-RADS to this April 8th, 2016 ultrasound?
A. No.
ATTORNEY ROSE: Object to

Page 275

the form.
THE WITNESS: I was -- I was -- I was not asked to provide an opinion on that ultrasound. I did look at it. There are technical requirements for -- you know, for the ultrasound, including sending images, which I don't believe were available.
BY ATTORNEY VAUGHN:
Q. What LI-RADS would you have given the ultrasound?
ATTORNEY ROSE: Object to the form.
THE WITNESS: I would have to go back and look, but it would -- based on the report and I believe my -- my recollection of that -- those images is concordant with the report, there was an observation there that was over a centimeter, which makes a -- which means a category -- which means positive, which should trigger

Page 276

diagnostic CT and MR, which happened in this case, so things are concordant.
BY ATTORNEY VAUGHN:
Q. And what was seen in the ultrasound when it was followed up by the CT was found to be noncancerous; correct?
ATTORNEY ROSE: Object to the form.
THE WITNESS: What we did not see on CT something that corresponding to what was seen on ultrasound.
ATTORNEY VAUGHN: I have no further questions.
THE VIDEO TECHNICIAN: Any additional questions?
ATTORNEY ROSE: No additional questions, thank you.
ATTORNEY VAUGHN: Thanks, Nina. Thank you, Dr. Chernyak. Enjoy the rest of your day.
THE VIDEO TECHNICIAN: That concludes today's deposition. The

Page 277

time is 3:10 p.m.
(Witness excused.)
(Deposition concluded at approximately 3:10 p.m.)